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INTERNATIONAL SEARCH REPORT

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This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 1 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
      ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :
      ☐ contained in the international application in written form.
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2. ☐ **Certain claims were found unsearchable** (See Box I).
3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,
   ☐ the text is approved as submitted by the applicant.
   ☒ the text has been established by this Authority to read as follows:

   INTERVENTIONAL AND DIAGNOSTIC CATHETER AND METHOD FOR USE

5. With regard to the **abstract**,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 8
   ☐ as suggested by the applicant.
   ☒ because the applicant failed to suggest a figure.
   ☐ because this figure better characterizes the invention.
   ☐ None of the figures.

INTERVENTIONAL AND DIAGNOSTIC CATHETER AND METHOD FOR USE

FIELD OF THE INVENTION

The present invention relates to catheters for use in cardiac diagnosis and treatment.

BACKGROUND OF THE INVENTION

It is known to place shunts or stents within a heart wall of a patient to permit oxygenated blood to flow directly from a heart chamber into a coronary blood vessel at a point downflow of an occlusion within the vessel. Such devices and methods for placing them are detailed in U.S. Patent Nos. 5,755,682, 5,908,029 and 5,944,019. Once these devices have been placed within the heart wall, diagnostic procedures involving the devices are sometimes necessary. To perform these procedures, a device that allows stabilization within the heart chamber and alignment with the device is useful. Improvements to existing catheters to provide the ability to stabilize the catheter within the heart chamber and facilitate the alignment of the catheter with the device in the heart wall are desirable.

SUMMARY OF THE INVENTION

One aspect of the present invention relates to a method for passing a fluid through a shunt located in the wall of a heart, the shunt providing fluid communication between a heart chamber and a coronary artery, with a hollow catheter. Another aspect of the present invention relates to a method of inserting a wire through a shunt located in the wall of a heart with a hollow catheter. A further aspect of the present invention relates to passing fluid through a shunt located in the wall of a heart, the shunt providing fluid communication between a heart chamber and a coronary artery, by injecting fluid into the heart chamber. A further aspect of the present invention relates to a catheter with a flexible, hollow, inner member to which a self expanding basket is attached. A further aspect of the present invention relates to a method of passing a radio-opaque contrast fluid through a shunt located in a heart wall, the shunt providing fluid communication between a heart chamber and a coronary artery. A further aspect of the present invention relates to inserting a wire into a coronary artery through a shunt located in a heart wall, the shunt

providing fluid communication between a heart chamber and the coronary artery. A still further aspect of the present invention relates to a catheter including an inner tube with a self-expanding basket and an outer sheath about the inner tube. A further aspect of the present invention relates to a catheter with a flexible inner member with a shunt locating element at a distal end and an outer sheath about the inner member.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of the description, illustrate several aspects of the invention and together with the description, serve to explain the principles of the invention. A brief description of the drawings is as follows:

FIG. 1 is a side view of an embodiment of an assembled catheter of the present invention.

FIG. 2 is a closer detail view the distal end of the assembled catheter of FIG. 1.

FIG. 3 is a side view of the outer sheath of the assembled catheter of FIG. 1.

FIG. 4 is an end view of the distal end of the outer sheath of FIG. 3.

FIG. 5 is a side view of the inner tube of the assembled catheter of FIG. 1.

FIG. 6 is a closer detail view of the distal end of the inner tube of FIG. 5

FIG. 7 is a schematic illustration with a heart in partial cutaway of an embodiment of a catheter of the present invention to catheterize the left ventricle of a patient's heart via the femoral artery.

FIG. 8 is a close-up of the heart of FIG. 7, showing a distal end of the catheter within the patient's left ventricle and a shunt in place in the wall of the patient's heart.

FIG. 9 is a cross-sectional view of the heart wall with a shunt in place between the heart chamber and a coronary artery and the distal end of the catheter with the stabilizing collapsible basket attached to the inner tube collapsed and retracted within the outer sheath.

FIG. 10 is the cross-sectional view of FIG. 9 showing the distal end of the outer sheath of the catheter retracted to permit the basket to expand.

FIG. 11 is the cross-sectional view of FIG.9, with the expanded basket now placed overlaying the protruding end of the shunt.

FIG. 12 is the cross-sectional view of FIG. 9 with the distal end of the outer sheath being extended toward the distal end of the inner tube causing the basket to collapse about the protruding end of the shunt and stabilize the catheter with respect to the shunt.

FIG. 13 is the cross-sectional view of FIG. 9, with the heavy arrows representing the flow of fluid being passed through the inner tube of the catheter and through the shunt, into the coronary artery.

FIG. 14 is the cross-sectional view of FIG. 9, showing a wire being inserted through the inner tube and through the shunt into the coronary artery.

FIG. 15 is a cross-sectional view of an alternative embodiment of a distal end of a catheter according to the present invention with the gripping element inverted within the inner tube.

FIG. 16 is a cross-sectional view of the catheter of FIG. 15 with a shaft inserted through the inner tube and forcing the gripping element from its inverted postion.

FIG. 17 is a cross-sectional view of the catheter of FIG. 16 with the shaft removed from the inner tube.

FIG. 18 is a cross-sectional view of the catheter of FIG. 17 with the gripping element retracted within the outer sheath.

FIG. 19 is an alternative embodiment of a distal end of a catheter according to the present invention for injecting dye into a heart chamber.

FIG. 20 is an alternative embodiment of a distal end of a catheter according to the present invention for injecting dye into a heart chamber.

FIG. 21 is an alternative embodiment of a distal end of a catheter according to the present invention for injecting dye into a heart chamber.

FIG. 22 is a side view of an alternative embodiment of a catheter in accordance with the present invention.

FIG. 23 is a cross-sectional view of a catheter body of the catheter of FIG. 22 taken at line 23-23.

FIG. 24 is a cross-sectional view of an alternative embodiment of an catheter body of a catheter in accordance with the present invention including four deflection wires.

FIG. 25 is a cross-sectional view of an alternative embodiment of an catheter body of a catheter in accordance with the present invention including two flat deflection tensioning members.

FIG. 26 is a cross-sectional view of an alternative embodiment of a catheter body of a catheter in accordance with the present invention including four flat deflection tensioning members.

FIG. 27 is a closer detail view of the distal end of the catheter body of the catheter of FIG. 22.

FIG. 28 is a cross-sectional view of the catheter body of the catheter of FIG. 24, taken along line 28-28.

FIG. 29 is a closer detail view of the distal end of the catheter body of the catheter of FIG. 22, showing both bending portions bent.

FIG. 30 is a view of the catheter of FIG. 29 with the first bend portion bent at a more acute angle.

FIG. 31 is a view of the catheter of FIG. 30 with the first bend portion bent at a more acute angle.

FIG. 32 is a schematic illustration with a heart in partial cutaway of a catheter including the catheter body shown in FIG. 22 used to catheterize the left ventricle of a patient's heart via the femoral artery.

FIG. 33 is a close-up of the heart of FIG. 32, showing a distal end of the catheter within the patient's left ventricle and a shunt in place in the wall of the patient's heart.

FIG. 34 is a schematic representation of the top cross-sectional view of the patient's left ventricle of FIG. 33, with the distal end of the catheter extending into the heart.

FIG. 35 is the heart and catheter of FIG. 34 with the first bending portion of the catheter bent in an arc.

FIG. 36 is the heart and catheter of FIG. 35 with the second bending portion of the catheter bent into an arc but not yet aligned with the shunt.

FIG. 37 is the heart and catheter of FIG. 36 with the distal end aligned with the shunt and a collapsible basket extending from within the catheter projecting over a leg of the shunt protruding into the left ventricle.

FIG. 38 is a side view of a handle in accordance with the present invention for use with the catheter of FIG. 1, with provision to apply tension to a single deflection wire.

FIG. 39 is a cross-sectional view of the handle of FIG. 38.

FIG. 40 is a cross-sectional view of an alternative handle for use with the catheter of FIG. 22 with provision to apply tension to two deflection wires.

FIG. 41 is a cross-sectional view of a second alternative handle for use with the catheter of FIG. 22 with provision to apply tension to a single deflection wire by a ratcheting mechanism.

FIG, 42 is a cross-sectional view of a third alternative handle for use with the catheter of FIG. 22 with provision to apply tension to a single deflection wire by an alternative ratcheting mechanism.

FIG. 43 is a cross-sectional view of a fourth alternative handle for use with the catheter of FIG. 22 with provision to apply tension to two deflection wires with the ratcheting mechanism of FIG. 41.

FIG. 44 is a cross-sectional view of a fifth alternative handle for use with the catheter of FIG. 22 with provision to apply tension to two deflection wires with the ratcheting mechanism of FIG. 42.

DETAILED DESCRIPTION

With reference to the detailed drawing figures in which identical elements are numbered identically throughout, a description of the preferred embodiment and various alternative embodiments will now be provided.

Once a shunt has been placed in the heart wall as described in U.S. Patent No. 5,944,019, there may arise the need to access the shunt for diagnostic or other reasons. For example, a physician may desire to inject radio-opaque chemical contrast material through the shunt to permit the use of cardiac imaging techniques to verify blood flow through the affected coronary artery downstream of the site of the shunt. Alternatively, it may be desirable to reach through the shunt to insert angioplasty tools to a site in the affected coronary artery downstream of the site of the shunt. Further, a physician may access the shunt to insert an arterial stent into the affected coronary artery at a site downstream from the shunt.

One of the least traumatic methods of accessing the heart and any shunts that might be implanted in the heart wall is with a catheter which enters the body via

insertion through the femoral artery in the patient's groin and is advanced through the femoral artery, descending aorta and ascending aorta, into the heart. Catheters for femoral insertion are known. However, when accessing a shunt placed in the heart wall of a patient without cardiopulmonary bypass, actually inserting a tool or other device into the shunt and the artery downstream of the shunt can be quite difficult. Without cardiopulmonary bypass, the patient's heart must necessarily be contracting during the catheterization, making the environment around the shunt quite dynamic. Known catheterization methods and apparatus do not address this issue.

As a follow-up procedure to the placement of a shunt through the heart wall to a coronary artery, it may be desirable to explore blood flow in the artery downstream of the shunt to determine the efficacy of the shunt in bypassing an arterial occlusion. The most common method of determining blood flow within a coronary artery is to insert a catheter directly into the artery and introduce a radio-opaque chemical contrast. Then, using radiographic or other cardiac imaging techniques, the flow of blood within the artery can be seen. This method is effective in the traditional vein graft arterial bypass situation as a new arterial pathway is created and any occlusions in the artery are thus avoided. A catheter can be inserted into the artery directly via the aorta and contrast injected directly into the artery through the catheter. When a cardiac shunt is in place, this method is less feasible, since a new arterial path bypassing the occlusion most likely has not been created, meaning that injecting contrast into the artery via the aorta will be injecting contrast at a site above the occlusion which necessitated the bypass procedure. Rather, the shunt permits blood from a heart chamber with oxygenated blood to flow directly into the coronary artery at a site downstream of the occlusion. For cardiac imaging techniques to be effective in determining blood flow in the affected artery where a shunt has been placed, the contrast is preferably injected though the shunt into the artery so that flow downstream of the occlusion can be explored. With a cardiac shunt in place, the cardiac catheter is preferably inserted through the aorta into the heart chamber for contrast to be injected into the shunt and the artery downstream of the shunt. However, because the movement of blood creates currents and eddies within the heart chambers, merely injecting a contrast within the chamber where the shunt is located may not ensure that sufficient contrast will flow through the shunt and into the artery to permit the blood flow to be adequately imaged. Instead, the

contrast is preferably injected directly into and through the shunt to permit effective imaging and flow analysis.

The present invention relates to a technique and devices for accessing shunts through heart walls. One aspect of the present invention relates to a technique and apparatus for allowing a catheter to enter the heart and align with or attach to an object imbedded in the heart wall with a high degree of certainty while a normal cardiac rhythm is maintained.

Now referring to FIGS. 1 through 6, an embodiment of a catheter apparatus 14 is shown. In FIGS. 3 and 4, outer sheath 108 of catheter 14 is shown in detail. At proximal end 140 of outer sheath 108, a hub 142 is attached. Hub 142 includes a pair of wings 144 extending radially from hub 142 to assist in the manipulation of the catheter and control the orientation of the curvature of catheter 14 when catheter 14 is inserted in a patient's body. Wings 144 extend on opposite sides of hub 142 and are oriented so as to be coplanar with primary curve 146 of catheter 14. Primary curve 146 and secondary curve 148 are designed to improve access to shunt 30 located in heart wall 32 within heart chamber 22. The relationship of primary curve 146 and secondary curve 148 of outer sheath 108, and the anatomic shape of the left ventricle, as well as the relationship of distal end 100 to shunt 30, are illustrated in FIGS. 7 and 8.

Primary curve 146 and secondary curve 148 combine to form a three-dimensional bend profile, as shown in FIGS. 3 and 4. Curves 146 and 148 separate outer sheath 108 and define three distinct segments. A first segment 145 extends from hub 142 to primary curve 146. First segment 145 is predominantly straight and preferably sized to extend from the femoral stick to the bottom of the left ventricle. A second segment 147 extends between primary curve 146 and secondary curve 148. A preferred length of the second segment is in the range of 1 to 9 centimeters. A third segment 149 is defined between secondary curve 148 and distal end 100. A preferred length of the third segment is in the range of 0.5 to 3 centimeters.

Outer sheath 108 is preferably made of a material that is flexible enough to allow catheter 14 to be straightened for insertion into and passage through the arterial path to the heart. At the same time, the material preferably has the elastic memory for returning to a pre-set shape, such as that shown in FIGS. 3 and 4. First segment 145, primary curve 146 and second segment 147 define a first plane AA. Primary curve 146 traverses an angle A in the range of one hundred forty to one

hundred eighty degrees, preferably approximately one hundred and sixty degrees. In plane AA, secondary curve 148 traverses an angle B in the range of sixty to one hundred twenty degrees, most preferably approximately eighty degrees. Third segment 149 is inclined from plane AA by an angle C in the range of ten to fifty degrees, most preferably approximately 30 degrees. As shown in FIG. 4, third segment 149 is offset in a clockwise direction from second segment 147. In other embodiments, third segment 149 can be offset in a counter-clockwise direction from second segment 147. As shown in FIG. 4, third segment 149 is aligned along line 115 that does not intersect first segment 145. However, line 115 is preferably within a plane 117 (shown in FIG. 3) that intersects first segment 145 at an angle D in the range of sixty to one hundred forty degrees, most preferably approximately one hundred degrees. The preferred embodiment has outer sheath 108 made of medical grade thermoplastic elastomer resin. Other materials with similar qualities may be used for the outer sheath. It is also anticipated that the outer sheath will have no preset bends but may be capable of being formed into the above-described shape once the catheter has been inserted into the left ventricle.

Referring now to FIGS. 5 and 6, inner tube 106 of catheter 14 is shown in detail. Inner catheter 106 includes a hub 152 at proximal end 150, a hollow catheter shaft 156 and distal end 104. At distal end 104 is attached expanding basket 102. Hub 152 includes a pair of wings 154 extending radially from hub 152 on opposite sides. Wings 152 permit the rotation and manipulation of inner tube 106 within outer sheath 108 and provide a reference for the user of catheter 14 as to the extent of movement and orientation of inner tube 106. Also at proximal end 150, beginning at hub 152, are a series of circumferential reference rings 158 about catheter shaft 156, spaced at one centimeter intervals for a distance of about 10 centimeters. Rings 158 aid the user in determining the relative extent of insertion of inner tube 106 within outer sheath 108. At distal end 104 of inner tube 106, a series of circumferential reference rings 160 are also placed about catheter shaft 156. Rings 160 include a radio-opaque material so that a fluoroscope or similar device can be used during the insertion and manipulation of catheter 14 to determine the location of distal end of inner tube 106 within the patient's body. Alternatively, or in addition to these reference rings, a fiber optical viewing system may be inserted within catheter shaft 156 with a viewing end located at the distal end of catheter 14

to provide visual imagery regarding the location of the distal end of catheter 14 and assist with its insertion and manipulation.

At distal end 104 of inner tube 106, a gripping element in the form of a self-expanding basket 102 is attached, as shown in FIG. 6. Basket 102 is shaped so that in a collapsed form 116 (shown in FIG. 12), it can be inserted within outer sheath 108 and completely contained within outer sheath 108. Provision may be made for permitting passage of objects such as an optical fiber viewing system through the distal end 104 of inner tube 106 to the distal end of catheter 14, while collapsed basket 116 is held within outer sheath 108. Basket 102 is preferably sized and shaped to allow overlay on first end 34 of shunt 30 in heart wall 32 (see FIG. 11). A frustal conical shape is shown in FIG. 6 and is the preferred embodiment but other shapes may also be suitable. Narrow end 112 of basket 102 is attached to distal end 104 of inner tube 106. Wide end 110 opens away from distal end 104 of inner tube 106 when basket 102 is allowed to expand. The preferred embodiment has basket 102 made of an elastic or super-elastic material such as nickel-titanium alloy. Other materials may be suitable for this application as well, as long as they have sufficient flexibility and resilience to permit being collapsed within outer sheath 108 and expending without additional influence when distal end 114 of outer sheath 108 is retracted. Alternatively, the gripping element may also be in the form of a lass-type snare.

Inner tube 106 is preferably made of a material with sufficient column strength to permit the axially movement of inner tube 106 within outer sheath 108 and controlled manipulation of distal end 104 and basket 102 attached thereto when catheter 14 is within the heart of a patient. The preferred embodiment has inner tube 106 made of a medical grade thermoplastic elastomer resin. Other plastic and metallic materials may be used provided they have the required physical characteristics. The material used to construct inner tube 106 preferably has a degree of lubricity with respect to the inner surface of outer catheter 108 to promote smoother relative movement of the two catheter components. If inner tube 106 material does not have a sufficient lubricity with respect to outer sheath 108 material, a low friction coating material can be applied to inner tube 106 prior to insertion into outer sheath 108.

Assembled catheter 14 including inner tube 106, outer sheath 108 and basket 102 is shown in FIGS. 1 and 2. Inner tube 106 is axially slidably contained within

outer sheath 108. In FIGS. 1 and 2, assembled catheter 14 is shown with basket 102 extended from distal end 114 of outer sheath 108 and in a fully expanded shape. The relationship of hub 152 of inner tube 106 and hub 142 of outer sheath 108 is shown by way of an example. Other relative orientations of the hubs are possible as long as the user is provided with a consistent reference as to the relationship of distal end 104 of inner tube 106 and distal end 114 of outer sheath 108.

Referring now to FIGS. 7 through 14, the use of one embodiment of the catheter of the present invention to perform an endovascular catheterization of a patient to access a shunt already in place in the left ventricle of the patient's heart will be described in detail.

A preferred embodiment of the current invention involves a method of passing a radio-opaque chemical contrast fluid through a shunt which has been installed in the wall of a patient's heart for the purpose of allowing oxygenated blood to flow from within a chamber of the heart directly into a coronary artery. A common reason for performing such a task is to enable imaging of the heart and the blood flow in the arteries surrounding the heart to determine the efficacy of the shunt in providing improved flow in the coronary artery.

To begin such a catheterization procedure, the distal end of the catheter 14 is inserted into the femoral artery 10 of a patient, via a site 12 in the patient's groin. The distal end of catheter 14 (shown in FIG. 8) is then advanced along femoral artery 10 in retrograde fashion. Upon reaching the upper most extension of the femoral artery, catheter 14 is then directed into the descending aorta 16. From descending aorta 16, catheter 14 is further advanced in retrograde fashion into the arch of aorta 18. Advancing through arch of aorta 18 retrograde, the distal end of catheter 14 passes through the ascending aorta 20 directly into the heart 26. Preferably, catheter 14 is advanced into a heart chamber 22 through the aortic valve 24. In FIGS. 7 and 8, the catheterization has been to the left ventricle of a patient's heart. First segment 145 is preferably of sufficient length to permit the insertion of catheter 14 in femoral artery 10 of a patient and extension of catheter 14 into patient's heart 26.

In FIG. 8, an enlarged view of the left ventricle of the patient is shown, with the catheter 14 entering chamber 22 from ascending aorta 20 and a shunt 30 in place in the wall 32 of heart chamber 22 being shown. Note that the basket 102 at distal end 104 of the inner tube 106 has remained in a collapsed position within the outer

sheath 108 as catheter 14 was inserted into heart chamber 22. Catheter 14 is advanced into heart 26 so that first segment 145 extends through aortic valve 24. Primary curve 146 rests substantially on the inferior wall of heart chamber 22 with second segment 147 extending superior within the chamber 22. Secondary curve 148 directs third segment 149 substantially anterior.

Shunt 30 is located on the anterior wall of chamber 22 and includes two ends, the first end 34 (shown in FIG. 9) extending into heart chamber 22 through heart wall 32, and the second end 36 (shown in FIG. 9) extending into a coronary artery 38 (illustrated is the left anterior descending coronary artery). It is anticipated that second end 36 of shunt 30 may be placed in any of the coronary arteries extending across the left ventricle. First end 34 and second end 36 have openings 44 and 46, respectively, which are connected by an open passageway 40 through the center of the shunt. The first end of the shunt extends into the heart chamber beyond wall 32 of the heart. This protrusion of first end 34 facilitates the stabilization of the diagnostic catheter 14. Opening 46 in second end 36 is directed so that blood flowing through shunt 30 from heart 26 will exit opening 46 in the direction of normal blood flow in coronary artery 38, the direction of normal blood flow being shown by the arrow in FIGS. 9 through 14. Also in FIGS. 9 through 14, an occlusion 42 is shown in coronary artery 38 upstream from shunt 30. It is anticipated that catheters conforming with the present invention may be used with other stent configurations as well (e.g., valved, unvalved, natural graft, mesh, flexible rigid, etc.) Also, catheters conforming with the present invention could be used to access side anastomosis sites.

Once third segment 149, secondary curve 148, second segment 147, primary curve 146 and a portion of first segment 145 of catheter 14 has entered heart chamber 22 via ascending aorta 20, distal end 100 can be directed to the vicinity of first end 34 of shunt 30 in heart wall 32, as shown in FIG. 9. The relative orientation of primary and secondary curves 146 and 148 and the angular offset of third segment 149 allow the distal end of catheter 14 to be directed to any of the interior of chamber 22. Preferably, third segment 149 is coaxially aligned with first end 34.

When in position near first end 34 of shunt 30, distal end 112 of outer sheath 108 is retracted with respect to distal end 104 of inner tube 106 to uncover collapsed

basket 116 attached to distal end 104 of inner tube 106, thus permitting collapsed basket 116 to expand to expanded basket 102, as shown in FIG. 10.

Expanded basket 102 includes a wide end 110 which is cone shaped and located opposite of a narrow end 112, narrow end 112 being attached to distal end 104 of inner tube 106. Expanded basket 102 is of an open design so that wide end 110 and narrow end 112 are in fluid and physical communication with each other. Once expanded basket 102 has been allowed to expand, expanded basket 102 is positioned so that wide end 110 of expanded basket 102 overlays upon first end 34 of shunt 34 in heart wall 32, as shown in FIG. 11.

After expanded basket 102 has been overlaid on first end 34 of shunt 30, distal end 114 of outer sheath 108 of catheter 14 is advanced with respect to distal end 104 of inner tube 106, so that distal end 114 of outer sheath 108 once again begins to interfere with expanded basket 102 and cause basket 102 to collapse, reverting back to collapsed basket 116. As expanded basket 102 collapses to become collapsed basket 116, wide end 110 is narrowed until it contacts first end 34 of shunt 30 and captively holds distal end 100 of catheter 14 to shunt 30, as shown in FIG. 12.

With catheter 14 now stabilized with respect to any movement of shunt 30 caused by movement of heart wall 32 due to normal contractions of heart 26, a radio-opaque fluid 120 can be passed through inner tube 106 of catheter 14 and flow straight through the distal end of catheter 14, into shunt 30 and into coronary artery 38, as shown in FIG. 13.

Alternatively, another embodiment of the method of the invention is shown in FIG. 14. In this embodiment, the steps are identical to the steps above, except, a wire 130 is passed though inner tube 106 and through shunt 30 into coronary artery 38 instead of radio-opaque fluid 120. Wire 130 can then be used as the foundation for performing a variety of other procedures within coronary artery 38 downstream of shunt 30. These procedures might include but not be limited to, inserting an arterial stent in the coronary artery, or performing angioplasty, atherectomy or pyroplasty in the coronary artery.

Further alternative embodiments for distal end 104 of inner tube 106 are shown in FIGS. 15 through 21. FIGS. 15 through 18 illustrate a trumpet 202, which operates in a similar fashion to basket 102. Trumpet 202 includes a narrow end 212 and a wide end 214, with narrow end 212 attached to distal end 104 of inner tube

106. FIG. 15 shows trumpet 202 configured for insertion into a patient, with wide end 214 inverted within the hollow interior of inner tube 106. Once the catheter 14 is positioned within heart chamber 22, a shaft 215 is extended through the interior of inner tube 106 to eject wide end 214 and allow trumpet 202 to expand, as shown in FIG. 16. Shaft 215 is then withdrawn from catheter shaft 156, as shown in FIG. 17 allowing trumpet 202 to be used in the same fashion as described above with regard to expanded basket 102 to capture end 34 of shunt 30. For withdrawal from heart chamber 22, wide end 214 is retracted within distal end 100 of outer sheath 108, as shown in FIG. 18.

FIGS. 19 through 21 show alternative embodiments of devices that may be attached at distal end 104 of inner tube 106 for injecting dye into heart chamber 22. FIG. 19 shows a bullet or torpedo shaped inner catheter distal end device 220 with a tapered or narrowed waist 226 attached at distal end 104 of inner tube 106. At the extreme distal end of device 220 is an opening 222 and along device 220 extending radially beyond outer sheath 108 are a series of smaller openings 224. The openings 222 and 224 allow fluid to be injected to heart chamber 22 through inner tube 106. Inner catheter distal end device 230, shown in FIG. 20, provides an end to inner tube 106 cylindrically shaped with a series of similarly sized openings 232 along the sides and at the extreme distal end of the device. Device 230 is attached to distal end 104 of inner tube 106 and permits fluid to be injected through catheter 14 into heart chamber 22. FIG. 21 shows a balloon shaped inner catheter distal end device 240 attached to distal end 104 of inner tube 106. Device 240 incorporates a series of spaced-apart openings 242 which permit fluid to be injected through catheter 14 into heart chamber 22. Device 240 is held collapsed within outer sheath 108 until outer sheath 108 has entered heart chamber 22. Inner tube 106 is then extended relative to outer sheath 108 as shown in FIG. 21, allowing device 240 to expand into a balloon shape.

Referring now to FIGS. 22 and 27, a catheter 310 with an outer sheath or catheter body 312 including a proximal end 314 and a distal end 316 is shown. Attached to catheter 310 at proximal end 314 is a handle 318. Catheter body 312 includes a distal segment 322, a first bending portion 324, a mid segment 326, a second bending portion 328 and a proximal segment 330. Segments 322, 326 and 330 are made from a flexible material to permit catheter 310 to be introduced into a patient's vascularity and maneuvered to a desired location without damaging the

vessels. Bending portions 324 and 328 are made of a similar material with a lower durometer than segments 322, 326 and 330, meaning pending portions 324 and 328 are more easily bent, while segments 322, 326 and 330 are relatively more rigid. Bending portions 324 and 328 may be made of material of the same durometer, or alternatively, first bending portion 324 may be made of a lower durometer material than second bending portion 328. Handle 318 includes two tensioning mechanisms 320, discussed in more detail below, and an access port 332 allowing items to be introduced into catheter 310.

Referring now to FIG. 23, a cross-section of catheter body 312 taken at line 23-23 in FIG. 22 is shown. Catheter body 312 includes an outer wall 334 which defines a central lumen 336 having a longitudinal central axis 338. Outer wall 334 defines an inner diameter ID and an outer diameter OD separated by a wall thickness T. Inner diameter ID is preferably at least 50% as large as outer diameter OD, more preferably at least 75% as large as outer diameter OD. Within wall thickness T of outer wall 334 are a first wire 342 in a first wire lumen 340 and a second wire 346 in a second wire lumen 344. First wire lumen 340 extends at least from handle 318 to a point distal to first bending portion 324. First wire 342 is attached to a first tensioning mechanism 320 in handle 318 and extends to a point immediately distal to first bending segment 324, where it is anchored within outer wall 334. First wire 342 is sized to slide freely within first wire lumen 340 except where first wire 342 is anchored to outer wall 334. A second wire 346 within a second wire lumen 344 is located in outer wall 334, offset from first wire 342 by an angle 348. Second wire 346 is attached to a second tensioning mechanism 320 in handle 318 and extends to a point immediately distal to second bending segment 328, where it is anchored within outer wall 334. Second wire 346 is sized to slide freely within second wire lumen 344 except where second wire 346 is anchored to outer wall 334. Applying tension to first wire 342 will cause first bending portion 324 to bend in an arc along a first plane 341 defined by central axis 338 of catheter body 312 and first wire lumen 340 in first bending segment 324. Applying tension to second wire 346 will cause second bending portion 328 to bend in an arc along a second plane 345 defined by central axis 338 and second wire lumen 344 in second bending portion 328. Angle 348 defines the degree of angular separation between planes 341 and 345.

Alternatively, catheter 310 may include only first wire 342 within first wire lumen 340, with wire 342 anchored to outer wall 334 immediately distal first bending segment 324 and attached to a tensioning mechanism 320 within handle 318. By using material of lower durometer in first bending portion 324 relative to the material used in second bending segment 328, applying tension to wire 342 will initially cause first bending portion 324 to bend in an arc along plane 341. As first bending portion 324 nears its degree of maximum bend, second bending portion 328 will begin to bend in an arc along plane 341.

FIGS. 24 through 26 and 28 show several alternative embodiments of a catheter in accordance with the present invention. All of these alternative embodiments include an outer wall 334 defining a central lumen 336 having a longitudinal central axis 338. FIG. 24 shows a first alternative catheter body 412 which includes four wire lumens 442, 446, 450 and 454, with four wires 444, 448, 452 and 456, respectively, equally spaced apart about outer wall 336. Each wire 444, 448, 452 or 456 is anchored immediately distal of a bending portion. FIG. 28 is a longitudinal cross-section taken along line 28-28 in FIG. 24 and shows an example of how wires 442 and 452 might be anchored to outer wall 334 to provide bending in two directions of first bending portion 324. By having wires 442 and 452 within wire lumens 440 and 450 which both line in a plane 441 including by central axis 338, first bending portion 324 can be bent up by applying tension to wire 442, or down by applying tension to wire 452. Wires 444 and 454 are similarly opposed and attached immediately distal of second bending portion 328, allowing second bending portion to be moved toward either wire by applying tension to that wire.

FIGS. 25 and 26 show alternative embodiments 512 and 612, respectively, of a catheter body in accordance with the present invention. Catheter bodies 512 and 612 incorporate flat tensioning members 542, 546, 642, 646, 650 and 656, in place of the round wires in the embodiments in the earlier FIGS. Catheter body 512 in FIG. 25 is similar to catheter 310 in FIG. 23, including an outer wall 334 defining a central lumen 336 with a central axis 338. A first tensioning member 542 is within a first tensioning lumen 540 and a second tensioning member 546 is within second tensioning lumen 544. Applying tension to first tensioning member 542 will cause first bending portion 324 to bend in an arc along a first plane 541 defined by central axis 338 of catheter body 512 and first tensioning lumen 540 in first bending segment 324. Applying tension to second tensioning member 546 will cause second

bending portion 328 to bend in an arc along a second plane 545 defined by central axis 338 and second tensioning lumen 544 in second bending portion 328. Angle 548 defines the degree of angular separation between planes 541 and 545.

Catheter body 612 in FIG. 26 is similar to catheter body 412 in FIG. 24, with four tensioning members 642, 646, 650 and 656, within four tensioning lumen 640, 644, 648 and 654, spaced about outer wall 334.

FIGS. 29 through 31 illustrate in more detail the angles through which bending segments of catheter 310 may be bent by applying tension to wires or tensioning members within outer wall 334. Second bending portion 328 is bent through an angle to form a primary curve 374. First bending portion 324 is bent through an angle to form a secondary curve 376. Primary curve 374 and secondary curve 376 lie in planes 345 and 341, respectively, and are thus offset from each other by angle 348. This angular offset allows distal segment 322 to overlap and cross proximal segment 330 as shown in FIG. 31.

Primary curve 374 traverses an angle in the range of one hundred forty to one hundred eighty degrees, preferably approximately one hundred and sixty degrees. Secondary curve 376 traverses an angle in the range of sixty to one hundred twenty degrees, most preferably approximately eighty degrees. As shown in FIG. 23, angle 348 is offset in a clockwise direction from plane 341 to plane 345. In other embodiments, angle 348 can be offset in a counter-clockwise direction, such that distal segment 322 in FIG. 31 would pass on the other side of proximal segment 330.

Proximal segment 330 is predominantly straight and preferably sized to extend from a femoral stick to a desired site within a patient's body. Length of segments 322 and 324 will vary depending on the site to be accessed within a patient's body. For use of catheter 310 to access sites within a patient's heart, length of mid segment 326 is preferably in the range of 1 to 9 centimeters. Similarly, for use of catheter 310 to access sites within a patient's heart, length of distal segment 322 is preferably in the range of 0.5 to 3 centimeters.

Referring now to FIGS. 32 through 37, the use of one embodiment of the catheter of the present invention to perform an endovascular catheterization of a patient to access a shunt already in place in the left ventricle of the patient's heart will be described in detail.

To begin such a catheterization procedure, distal end 316 of catheter 310 is inserted into the femoral artery 354 of a patient, via a site 352 in the patient's groin. Distal end 316 of is then advanced along femoral artery 354 in retrograde fashion. Upon reaching the upper most extension of the femoral artery, catheter 310 is then directed into the descending aorta 356. From descending aorta 356, catheter 310 is further advanced in retrograde fashion into the arch of aorta 358. Advancing through arch of aorta 358 retrograde, distal end 316 of catheter 310 passes through the ascending aorta 360 directly into the heart 350. Preferably, catheter 310 is advanced into a heart chamber 364 through the aortic valve 362. In FIGS. 32 and 33, the catheterization has been to the left ventricle of a patient's heart. Proximal segment 330 is preferably of sufficient length to permit the insertion of catheter 310 in femoral artery 354 of a patient and extension of catheter 310 into patient's heart 350. In FIG. 33, an enlarged view of the left ventricle of the patient is shown, with the catheter 310 entering chamber 364 from ascending aorta 360 and a shunt 370 in place in the wall 366 of heart chamber 364 being shown.

Once distal segment 322, first bending portion 324, mid segment 326, second bending portion 328 and a portion of proximal segment 330 of catheter 310 has entered heart chamber 364 via ascending aorta 360, a sequence of manipulating bending portions 324 and 328 into primary and secondary curves 374 and 376 is shown in FIGS. 34 through 37. FIG. 34 shows catheter 310 in place and unbent within heart chamber 364. Tension is applied to first wire 342 to form first bending portion 324 into secondary curve 376, as shown in FIG. 35. Tension is next applied to second wire 48 to begin forming second bending portion 328 into primary curve 374, as shown in FIG. 35. Once primary curve 374 is fully formed by bending second bending portion 328, catheter 310 is advanced further into heart chamber 364 so that second bending portion 28 is resting against wall 366, providing support to improve the stability and manipulation of catheter 310 to place distal end 316 proximate shunt 370 in heart wall 366. As shown in FIG. 37, catheter 310 has had bending portions 324 and 328 formed into secondary and primary curves 374 and 376, respectively, which are resting against heart wall 366 to position distal end 316 proximate shunt 370 and allow a snare such as basket 372 or some other type of snare, to be extended from within central lumen 36 and capture and end of shunt 370 extending into chamber 364.

Positioning of distal end 316 proximate the shunt within heart wall 366 can be accomplished by rotating catheter handle 318 and varying the degree of curvature of secondary curve 376 and primary curve 374 by varying the tension in wires 342 and 346, respectively. Once a snare such as basket 372 has been attached to shunt 370, distal end 316 can be moved directly proximate shunt 370 to allow radio-opaque contrast to be injected through shunt 370, to access coronary artery 368 at a point downflow from the shunt 370 or to perform other diagnostic procedures.

It is anticipated that catheter 310 can be used to access other locations within a patient's body and that the length of proximal segment 330, mid segment 326 and distal segment 322 may be varied to suit the location desired to be accessed. Additionally, amount of bend available to form primary curve 374 and secondary curve 376 in bending portions 328 and 324 may be varied to suit the location to be accessed. Further, angle 348 defining the angular separation between first plane 341 and second plane 345 may be varied to suit accessing a different location. While its preferred use is for coronary diagnostic procedures, the present invention can be used for other medical procedures where precise control of a catheter tip is desired. It will be appreciated that the size, shape and bend locations can be varied to correspond to different applications.

Referring now to FIGS. 38 and 39, handle 18 is shown in detail for use with catheter 310, permitting tension to be applied to wires or tensioning members within outer wall 334. Handle 318 is shown with two slides 320, each of which may be moved along an opening 380 and which are attached to first and second wires 342 and 346 by anchors 382. Moving a slide 320 proximally along opening 380 applies tension to the wire attached to that slide, while moving the same slide 320 distally will release tension in the attached wire. Anchors 382 include an extension 378 which rides along an internal guide 384. As shown in FIGS. 38 and 39, catheter body 312 extends through handle 318, with proximal end 314 at the rear of handle 318 where a port 332 is mounted. Port 332 allows access to the central lumen 336 for inserting tools, diagnostic devices, fluids or other similar objects into catheter 310 for insertion within the patient's body at the site being accessed with catheter 310. While slides 320 are shown on opposite sides of handle 318, slides 320 may be attached to wires 342 and 346 which have an angular offset of less than one hundred eighty degrees. Handle 318 may be used with any single or dual wire embodiment of a catheter in accordance with the present invention. A locking mechanism, such

as a thumb screw or other releasable device, not shown in the FIGS., may be used to hold slide 320 so that the desired amount of tension is being applied to wire 342 or 346.

Referring now to FIGS. 40 through 44, FIG. 40 shows an alternative handle 418, which provides a single slide 320 for applying tension to a wire 342. FIG. 41 shows another alternative handle 518, similar to 418 in that only a single actuator 388 is provided to apply tension to wire 342. Actuator 388 actuates a ratcheting mechanism 386 to apply tension to wire 342 and hold a desired amount of tension. When the procedure being performed with catheter 310 is complete, the ratchet releases the tension on the wire, allowing the bending segments of the catheter to return to their original shapes. Sliding actuator 388 proximally and releasing it causes ratchet 386 to increase and hold tension in wire 342. Sliding actuator 388 proximally and holding actuator 388 in this position releases the tension in wire 342.

FIG. 42 also shows an alternative handle 618, which is adapted to provide tension to a single wire 342 of catheter 310. Handle 618 includes a trigger-style actuator 392 to apply tension to wire 342. Actuator 392 actuates a ratcheting mechanism 390 to apply, hold and release tension on wire 342, in a similar fashion as that described above with regard to actuator 388 and ratchet 386. FIG. 43 shows a further alternative handle 718, which incorporates two actuators 388 actuating two ratcheting mechanisms 386 to apply, hold and release tension on wires 342 and 346. FIG. 44 shows a further embodiment handle 818, which incorporates two trigger-style actuators 392 actuating two ratcheting mechanisms 390 to apply, hold and release tension on wires 342 and 346.

Additional embodiments of handle 318 are anticipated which will incorporate actuators and tensioning mechanisms for each of the wires or tensioning devices which may be within outer wall 334 of a catheter 310.

Having described preferred aspects and embodiments of the present invention, modifications and equivalents of the disclosed concepts may readily occur to one skilled in the art. However, it is intended that such modifications and equivalents be included within the scope of the claims which follow.

WHAT IS CLAIMED IS:

1. A catheter comprising:

a hollow cored catheter body defining an inner wall, an outer wall, a distal end and a proximal end, a hub attached to the proximal end, the hub including an opening aligned with the hollow core of the catheter body;

wherein the catheter body is substantially linear and may be formed into a shape including a primary curve and a secondary curve, a first length between the hub and the primary curve, a second length between the primary curve and the secondary curve, and a third length between the secondary curve and the distal end of the outer sheath;

the primary curve traversing an arc in the range of one hundred forty to one hundred eighty degrees and the first and second lengths of the hollow cored member defining a first plane; and

the second arc traversing an arc in the range of sixty to one hundred twenty degrees and a second plane defined by the second and third lengths of the hollow cored member lies at an angle in the range of ten to fifty degrees from the first plane.

2. The catheter of claim 1, wherein the primary and secondary curves of the catheter body are made of a deformable shape memory material such that the catheter body may be substantial linear for advancement within a lumen of a patient and the catheter body forms the primary and secondary curves when the shape memory material enters a cavity with the patient.

3. The catheter of claim 1, wherein the primary and secondary curves of the catheter body are made of a deformable material, the catheter body includes at least one tensioning member lumen parallel to the hollow core, the hub including at least one tensioning mechanism, a tensioning member within each tensioning member lumen extending from the tensioning mechanism to a point distal one of the primary or secondary curves, such that tensioning the tensioning members causes the catheter body to form at least one of the primary and secondary curves.

4. The catheter of claim 3, wherein the catheter body includes a first tensioning member lumen and a second tensioning member lumen;

a first tensioning member is within the first tensioning member lumen extending from a first tensioning mechanism to a first point distal the primary curve;

a second tensioning member is within the second tensioning member lumen extending from a second tensioning mechanism to a second point distal the secondary curve; and

tensioning the first tensioning member forms the catheter body into the primary curve and tensioning the second tensioning member forms the catheter body into the secondary curve.

5. A method of passing a fluid through a shunt in a heart wall of a heart, the heart wall having inner and outer sides, the shunt being in fluid communication with a coronary artery, the shunt extending at least partially through the heart wall, the method comprising the steps of:

providing a hollow catheter, a distal end of which extends into a chamber of the heart where the shunt is located;

aligning the distal end of the catheter with the first end of the shunt; and

passing the fluid through the distal end of the catheter and through the shunt into the coronary artery.

6. The method of claim 5, wherein a portion of the shunt protrudes beyond the inner side of the heart wall into a chamber of the heart, and the method further comprising releasably attaching the distal end of the catheter to the protruding portion of the shunt, and passing the fluid through the distal end of the catheter and through the shunt into the coronary artery after attachment.

7. A method of inserting a wire through a shunt in a heart wall of a heart, the heart wall having inner and outer sides, the shunt being in fluid communication with a coronary artery, the shunt extending at least partially through the heart wall, the method comprising the steps of:

providing a hollow catheter, a distal end of which extends into a chamber of the heart where the shunt is located;

aligning the distal end of the catheter with the shunt; and

inserting the wire through the distal end of the catheter and through the shunt into the coronary artery.

8. The method of claim 7, wherein a portion of the shunt protrudes beyond the inner side of the heart wall into a chamber of the heart, and the method further comprising releasably attaching the distal end of the catheter to the protruding portion of the shunt, and inserting the wire through the distal end of the catheter and through the shunt into the coronary artery after attachment.

9. A method of passing diagnostic fluid through a shunt in a heart wall, the shunt extending through the heart wall and providing fluid communication between a heart chamber and a blood vessel located adjacent an outer side of the heart wall, the method comprising the steps of:

positioning a catheter within the heart chamber; and

while the catheter is in the heart chamber, directing the diagnostic fluid from the catheter through the shunt and into the vessel.

10. The method of claim 9, further comprising the step of aligning a distal end of the catheter with the shunt prior to directing the diagnostic fluid through the catheter.

11. The method of claim 10, further comprising the step of releasably attaching a distal end of the catheter with the shunt prior to directing the diagnostic fluid through the catheter.

12. The method of claim 9, wherein a portion of the catheter proximate the distal end comprises a narrow-waisted structure with one or more openings spaced about the structure and the catheter includes an opening at the distal end, the openings allowing the diagnostic fluid to pass into the heart chamber.

13. The method of claim 9, wherein a portion of the catheter proximate the distal end comprises a cylindrical structure including one or more openings spaced about the structure and the catheter includes an opening at the distal end, the openings allowing the diagnostic fluid to pass into the heart chamber.

14. The method of claim 9, wherein a portion of the catheter proximate the distal end comprises a balloon-shaped structure including one or more openings spaced

about the structure, the openings allowing the diagnostic fluid to pass into the heart chamber.

15. The method of claim 9, wherein the diagnostic fluid is a radio-opaque contrast fluid.

16. A catheter comprising:

a flexible first catheter member defining at least one lumen, the first catheter having a distal end and a proximal end;

a self-expanding element mounted to the distal end of the first catheter, the self-expanding element being movable between an expanded orientation and a compressed orientation, the self-expanding element being sized for insertion through a patient's vasculation when in the compressed orientation, the self-expanding element defining an inner cavity when in the expanded orientation, the inner cavity having a first cross-sectional area adjacent the distal end of the first catheter member and a second cross-sectional area distally spaced apart from the distal end of the first catheter member, the second cross-sectional area being larger than the first cross-sectional area.

17. The catheter of claim 16, further comprising an outer sheath for moving the self-expanding element between the expanded orientation and the compressed orientation.

18. The catheter of claim 17, wherein the self-expanding element comprises a mesh basket.

19. The catheter of claim 18, wherein the cavity defines a frustal conical shape in the expanded orientation having minor diameter at the distal end of the first catheter member and major diameter distally spaced apart from the distal end of the first catheter member.

20. The catheter of claim 17, wherein the cavity has a cross-sectional area that gradually increases as the self-expanding element extends distally from the distal end of the first catheter member.

21. The catheter of claim 17, wherein the outer sheath is slidable is an axial direction relative to the first catheter member.

22. A method of passing radio-opaque contrast fluid through a shunt in a heart wall, for the purpose of enhancing cardiac imaging techniques, the method comprising:

(a) providing a catheter including:

(1) an outer sheath with a continuous hollow core, defining inner and outer walls, and distal and proximal ends;

(2) an inner tube with a continuous hollow core including a collapsible, gripping element at a distal end,

(3) the gripping element having a narrow end attached to the distal end of the inner tube and an expanding wide end positioned opposite the narrow end, the narrow end including an opening aligned with the hollow core of the inner tube;

(4) the inner tube being slidably contained within the outer sheath; and,

(5) the distal end of the inner tube being withdrawn into the distal end of the outer sheath so that the gripping element is maintained in a collapsed position;

(b) inserting a distal end of the catheter into a femoral artery of a patient;

(c) after inserting the catheter into the femoral artery, advancing the distal end along the femoral artery, through the descending aorta and the ascending aorta, and into a heart chamber containing oxygenated blood where the shunt in the heart wall is located;

(d) the shunt being in fluid communication with the heart chamber and a coronary artery, allowing oxygenated blood from the heart chamber to flow through the heart wall and into the coronary artery, wherein the heart wall defines inner and outer faces, and wherein the shunt has a first end including a portion protruding beyond the inner face and into the heart chamber, and a second end which is connected with the coronary artery;

(e) after directing the catheter into the heart chamber, directing the distal end of the catheter to a position proximate the portion of the first end of the shunt protruding into the heart chamber;

(f) after positioning the distal end of the catheter proximate the first end of the shunt, retracting the distal end of the outer sheath with respect to the distal end of the inner tube so as to extend the expanding gripping element beyond the distal end of the outer sheath and permit the gripping element to expand within the heart chamber;

(g) after allowing the gripping element to expand, directing the distal end of the inner tube with the gripping element attached proximate to and overlaying the protruding first end of the shunt;

(h) after positioning the gripping element proximate to and overlaying the protruding first end of the shunt, extending the outer sheath with respect to the inner tube, without disturbing the position of the gripping element, so that the inner wall of the outer sheath interferes with the gripping element, causing the gripping element to collapse about and securely hold the protruding first end of the shunt;

(i) after capturing the protruding first end of the shunt, passing the radio-opaque contrast material through the hollow core of the inner tube from the proximal end so that the radio-opaque contrast material flows through the catheter, through the gripping element, through the shunt and into the coronary artery;

(j) while passing the radio-opaque contrast material through the shunt into the coronary artery, performing a cardiac imaging technique to observe the magnitude and extent of blood flow in the coronary artery;

(k) while the protruding first end of the shunt is held by the gripping element, withdrawing the outer sheath with respect to the inner tube so that the inner wall of the outer sheath no longer holds the gripping element collapsed about and secured to the protruding first end of the shunt, allowing the gripping element to expand and release the protruding first end of the shunt;

(l) after the gripping element has released the protruding first end of the shunt, moving the distal end of the catheter to a position within the heart chamber not overlaying the protruding first end of the shunt and extending the outer sheath with respect to the inner tube so that the inner wall of the outer sheath causes the gripping element to collapse and the gripping element to be contained wholly within the outer sheath; and

(m) extracting the distal end of the catheter from the heart chamber, from the aorta and from the femoral artery, removing the catheter from the patient.

23. The method of claim 22, wherein the heart chamber containing oxygenated blood is the left ventricle.

24. A method of inserting a wire through a shunt in a heart wall connecting to a coronary artery, the method comprising:

(a) providing a catheter including:

(1) an outer sheath with a continuous hollow core, defining inner and outer walls, and distal and proximal ends;

(2) an inner tube with a continuous hollow core including a collapsible, self-expanding gripping element at a distal end,

(3) the gripping element having a narrow end attached to the distal end of the inner tube and an expanding wide end positioned opposite the narrow end, the narrow end including an opening aligned with the hollow core of the inner tube;

(4) the inner tube being slidably contained within the outer sheath; and,

(5) the distal end of the inner tube withdrawn into the distal end of the outer sheath so that the gripping element is maintained in a collapsed position;

(b) inserting the distal end of the catheter into a femoral artery of a patient;

(c) after inserting the catheter into the femoral artery, advancing the distal end along the femoral artery, through the descending aorta and the ascending aorta, and into a heart chamber containing oxygenated blood where the shunt in the heart wall is located;

(d) the shunt being in fluid communication with the heart chamber and the coronary artery, allowing oxygenated blood from the heart chamber to flow through the heart wall and into the coronary artery, wherein the heart wall defines inner and outer faces, and wherein the shunt has a first end extending through the heart wall, a portion of the first end protruding beyond the inner face and into the heart chamber, and a second end which is connected with the coronary artery;

(e) after directing the catheter into the heart chamber, directing the distal end of the catheter to a position proximate the portion of the first end of the shunt protruding into the heart chamber;

(f) after positioning the distal end of the catheter proximate the first end of the shunt, retracting the distal end of the outer sheath with respect to the distal end of the inner tube so as to extend the expanding gripping element beyond the distal end of the outer sheath and permit the gripping element to expand within the heart chamber;

(g) after allowing the gripping element to expand, directing the distal end of the inner tube with the gripping element attached proximate to and overlaying the protruding first end of the shunt;

(h) after positioning the gripping element proximate to and overlaying the protruding first end of the shunt, extending the outer sheath with respect to the inner tube, without disturbing the position of the gripping element, so that the inner wall of the outer sheath interferes with the gripping element, causing the gripping element to collapse about and securely hold the protruding first end of the shunt;

(i) after capturing the extended leg of the shunt, inserting the wire through the hollow core of the inner tube so that the wire extends through the catheter, through the gripping element and through the shunt into the coronary artery;

(j) while the protruding first end of the shunt is held by the gripping element, withdrawing the outer sheath with respect to the inner tube so that the inner wall of the outer sheath no longer holds the gripping element collapsed about and secured to the protruding first end of the shunt, allowing the gripping element to expand and release the protruding first end of the shunt;

(k) after the gripping element has been removed from the protruding first end of the shunt and while the wire extends through the inner tube and through the shunt into the coronary artery, moving the distal end of the catheter to a position within the heart chamber not overlaying the protruding first end of the shunt and retracting the distal and of the inner tube with respect to the distal end of the outer sheath so that the inner wall of the outer sheath causes the gripping element to collapse and the gripping element to be contained within the outer sheath, then withdrawing the inner tube from the outer sheath at the proximal end, leaving the outer sheath and the wire in place within the patient;

(l) with the outer sheath extending into the heart chamber and the wire extending through the catheter into the shunt, withdrawing the wire from the shunt and the outer sheath from the proximal end of the catheter; and

(m) extracting the distal end of the catheter from the heart chamber, from the aorta and from the femoral artery, removing the catheter from the patient.

25. The method of claim 24, wherein once the inner tube has been removed and while the wire extends through the hollow core of the outer sheath of the catheter and extends through the shunt, and the outer sheath extends into the heart chamber, performing angioplasty, atherectomy or pyroplasty at a site within the coronary artery downstream of the shunt.

26. The method of claim 24, wherein once the inner tube has been removed and while the wire extends through the hollow core of the outer sheath of the catheter and extends through the shunt, and the outer sheath extends into the heart chamber, inserting a stent at a site within the coronary artery downstream of the shunt.

27. The method of claim 24, wherein the heart chamber is the left ventricle.

28. A catheter comprising:

(a) an inner tube, including:

(1) a hollow cored member defining distal and proximal ends;

(2) an expanding, collapsible gripping element attached at the distal end, the gripping element having a narrow end attached to the distal end of the inner tube and an expanding wide end positioned opposite the narrow end and the narrow end including an opening aligned with the hollow core of the inner tube;

(3) a hub attached at the proximal end;

(4) the hub including an opening aligned with the hollow core of the inner tube;

(b) an outer sheath including:

(1) a hollow cored member defining an inner wall, an outer wall, a distal end and a proximal end;

(2) a hub attached to the proximal end;

(3) the hub including an opening aligned with the hollow core of the outer sheath; and

(c) wherein the inner tube is slidably contained within the inner wall of the outer sheath, so that when the distal end of the inner tube is contained with the

inner wall, the expanding gripping element is held in a collapsed position within the outer sheath.

29. The catheter of claim 28, wherein the hollow cored member of the outer sheath defines a primary curve and a secondary curve, a first length between the hub and the primary curve, a second length between the primary curve and the secondary curve, and a third length between the secondary curve and the distal end of the outer sheath.

30. The catheter of claim 29, wherein the primary curve traverses an arc in the range of one hundred forty to one hundred eighty degrees and the first and second lengths of the hollow cored member define a first plane, and the second arc traverses an arc in the range of sixty to one hundred twenty degrees in the direction of the first length of the hollow cored member and a second plane defined by the second and third lengths of the hollow cored member lies at an angle in the range of ten to fifty degrees from the first plane.

31. The catheter of claim 29, wherein the hollow cored member of the outer sheath is made of medical grade thermoplastic elastomer resin.

32. The catheter of claim 29, wherein the inner hollow member is made of medical grade thermoplastic elastomer resin.

33. The catheter of claim 29, wherein the inner hollow member is made of flexible metallic material.

34. The catheter of claim 29, wherein the collapsible gripping element is made of a Nickel Titanium alloy.

35. The catheter of claim 29, wherein the inner tube includes a radio-opaque marker band circumferentially placed about the inner tube at the distal end immediately adjacent to the gripping element and additional radio-opaque marker bands circumferentially about the inner tube equally spaced with respect to the distal marking band.

36. The catheter of claim 29, wherein the inner tube hub incorporates a strain relief device.

37. The catheter of claim 29, wherein the hollow cored member of the outer sheath is substantially linear and may be formed into a shape including a primary curve and a secondary curve, a first length between the hub and the primary curve, a second length between the primary curve and the secondary curve, and a third length between the secondary curve and the distal end of the outer sheath, wherein the primary curve traverses an arc in the range of one hundred forty to one hundred eighty degrees and the first and second lengths of the hollow cored member define a first plane, and the second arc traverses an arc in the range of sixty to one hundred twenty degrees in the direction of the first length of the hollow cored member and a second plane defined by the second and third lengths of the hollow cored member lies at an angle in the range of ten to fifty degrees from the first plane.

38. A catheter comprising:

a flexible inner tube defining at least one lumen, the inner tube having a distal end and a proximal end;

a shunt locating element mounted to the distal end of the inner catheter, the shunt locating element being sized for insertion through a patient's vasculation, the shunt locating element being configured to releasably attach to a shunt; and

an outer sheath mounted about the inner tube, the inner tube being axially slidable with respect to the outer sheath.

39. The catheter of claim 38, wherein the shunt locating element is a self-expanding basket.

40. A catheter comprising:

a hollow outer sheath defining an interior and an exterior;

a hollow, flexible inner tube defining at least one lumen, the inner tube having an interior space, a distal end and a proximal end;

the inner tube slidably held within the interior of the outer sheath;

a hollow device mounted to the distal end of the inner tube, the device providing fluid communication through the device via a series of axially spaced apart openings.

41. The catheter of claim 40, wherein the device is bullet shaped and includes an opening defined at an end opposite the distal end of the inner tube.

42. The catheter of claim 40, wherein the device is cylindrical in shape and includes an opening defined at an end opposite the distal end of the inner tube.

43. The catheter of claim 40, wherein the device is collapsible, self-expanding and generally spherical in shape, the device having a diameter larger than the interior of the outer sheath and collapsible to fit within the interior of the outer sheath.

44. A catheter comprising:

a catheter body having a pre-set shape including a primary curve and a secondary curve, the pre-set shape also including an intermediate segment connecting the primary and secondary curves and a distal-most segment projecting from the secondary curve, the intermediate segment and the primary curve defining a plane, the distal-most segment being offset from the plane, and the pre-set shape being sized to fit within the left ventricle of a human.

45. A catheter comprising:

a catheter body including a distal end, a proximal end, a pre-set primary curve and a pre-set secondary curve, a first segment extending from the proximal end to the primary curve, a second segment extending from the primary curve to the secondary curve, and a third segment extending from the secondary curve to the distal end, the third segment being co-linear with a line offset from the first segment, the line being positioned within a plane that intersects the first segment at an angle in the range of sixty to one hundred forty degrees.

46. A catheter comprising:

a catheter body including a distal end and a proximal end, the catheter body being shapeable proximate the distal end to form a primary curve and a secondary curve;

the catheter body including a first segment extending from the proximal end to the primary curve, a second segment extending from the primary curve to the secondary curve, and a third segment extending from the secondary curve to the distal end, the third segment being co-linear with a line offset from the first segment, the line being positioned within a plane that intersects the first segment at an angle in the range of sixty to one hundred forty degrees.

47. A catheter comprising:

a body extending between a distal end and a proximal end;

the body including a central lumen defined by an outer wall, the central lumen extending longitudinally from the proximal end to the distal end and permitting fluid communication between the ends, the outer wall made of a resilient, flexible material and including a bend portion adjacent the distal end where the outer wall has greater flexibility;

the body further including a tensioning member lumen extending longitudinally through the outer wall;

a tensioning member within the tensioning member lumen extending from the proximal end toward the distal end to a point distal to the bend portion of the body and anchored to the outer wall within the tensioning member lumen at the point;

wherein applying tension to the tensioning member deflects the distal end along a plane defined by the tensioning member and a central axis of the body, in the direction of the tensioning member, the bend portion forming a bend along the plane.

48. The catheter of claim 47, wherein the bending portion is a first bending portion and the catheter body also includes a second bending portion located between the proximal end and the first bending portion, the bend formed by the first bending portion is a first bend and tensioning the tensioning member further causes the seconding bending portion to form a second bend along the plane and deflect the distal end of the catheter.

49. The catheter of claim 48, wherein the first bending portion is made of a material with a lower durometer than the second bending portion so that tensioning

the tensioning member causes the first bending portion to bend before the second bending portion.

50. The catheter of claim 49, wherein tensioning the tensioning member bends the first bend to a maximum arc of approximately one hundred eighty degrees.

51. The catheter of claim 49, wherein tensioning the tensioning member bends the first bending to a maximum arc of approximately one hundred sixty degrees.

52. The catheter of claim 49, wherein tensioning the tensioning member bends the second bend to a maximum arc of approximately one hundred degrees.

53. The catheter of claim 49, wherein tensioning the tensioning member bends the second bend to a maximum arc of approximately eighty degrees.

54. The catheter of claim 48, wherein a handle is mounted to body at the proximal end, the handle allowing fluid communication with the central lumen and providing a tensioning mechanism for tensioning the tensioning member.

55. The catheter of claim 54 wherein the tensioning mechanism further includes a releasable lock for maintaining a desired amount of tension in the tensioning member.

56. The catheter of claim 47, wherein the bending portion is a first bending portion and a second bending portion is located between the first bending portion and the proximal end, the tensioning member lumen is a first tensioning member lumen and a second tensioning member lumen extends parallel to the first tensioning member lumen angularly displaced about the outer wall from the first tensioning member lumen, the tensioning member is a first tensioning member and a second tensioning member is within the second tensioning member lumen and anchored to the outer wall within the second tensioning member lumen at a point distal to the second bend portion, so that a tension applied to the second tensioning member deflects the distal end along a second plane defined by the second tensioning member and the central axis of the body in the direction of the second tensioning member, the second bend portion forming an bend along the second plane.

57. The catheter of claim 56, wherein tensioning the first tensioning member bends the first bend to a maximum arc of approximately one hundred eighty degrees.

58. The catheter of claim 56, wherein tensioning the first tensioning member bends the first bend to a maximum arc of approximately one hundred sixty degrees

59. The catheter of claim 56, wherein tensioning the second tensioning member bends the second bend to a maximum arc of approximately one hundred degrees, preferably approximately eighty degrees.

60. The catheter of claim 56, wherein tensioning the second tensioning member bends the second bend to a maximum arc of approximately eighty degrees.

61. The catheter of claim 56, wherein a handle is mounted to the body at the proximal end, the handle allowing fluid communication with the central lumen and providing a tensioning mechanism for tensioning the first and second tensioning members independently.

62. The catheter of claim 61, wherein the handle further includes a releasable lock for independently maintaining a desired amount of tension in the first tensioning member and in the second tensioning member.

63. The catheter of claim 56, wherein a distal segment is defined between the distal end and the first bending portion, a mid segment is defined between the first and second bending portions and a proximal segment is defined between the second bending portion and the proximal end, the distal segment having a length between 0.5 centimeters and 3 centimeters.

64. The catheter of claim 63, wherein the mid segment has a length between 1 centimeter and 9 centimeters.

65. The catheter of claim 56, wherein the angular displacement between the first and second tensioning members is between approximately ten degrees and approximately fifty degrees. approximately thirty degrees.

66. The catheter of claim 56, wherein the angular displacement between the first and second tensioning members is approximately thirty degrees.

67. A method of accessing a location on a heart wall comprising the steps of:

providing a catheter including a body with a central lumen defined by an outer wall, a distal end, a proximal end, a first bending portion and a second bending portion;

advancing the distal end, the first bending portion and the second bending portion into a chamber of a heart including the heart wall with the location to be accessed;

tensioning a first tensioning member within a first tensioning member lumen in the outer wall, causing the first bending portion to bend in an arc and deflect the distal end of the catheter; and

tensioning a second tensioning member within a second tensioning member lumen in the outer wall, causing the second bending portion to bend in an arc and deflect the distal end of the catheter to align the distal end with the location.

68. A method of accessing a location on a heart wall comprising the steps of:

providing a catheter including a body with a central lumen defined by an outer wall, a distal end, a proximal end, a first bending portion and a second bending portion, the first bending portion made from a lower durometer material than the second bending portion;

advancing the distal end, the first bending portion and the second bending portion into a chamber of a heart including the heart wall with the location to be accessed;

tensioning a tensioning member within a tensioning member lumen in the outer wall, causing the first bending portion to bend in an arc and deflect the distal end of the catheter; and

further tensioning the tensioning member causing the second bending portion to bend in an arc and deflect the distal end of the catheter to align the distal end with the location.

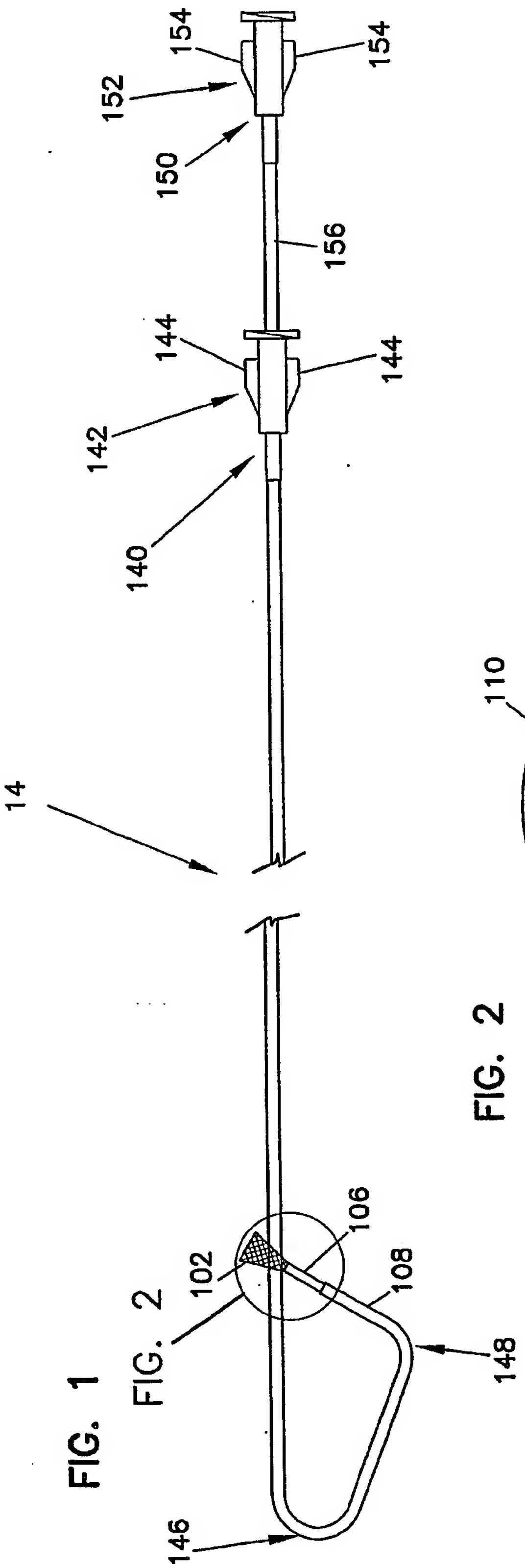
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FIG. 2
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FIG. 1

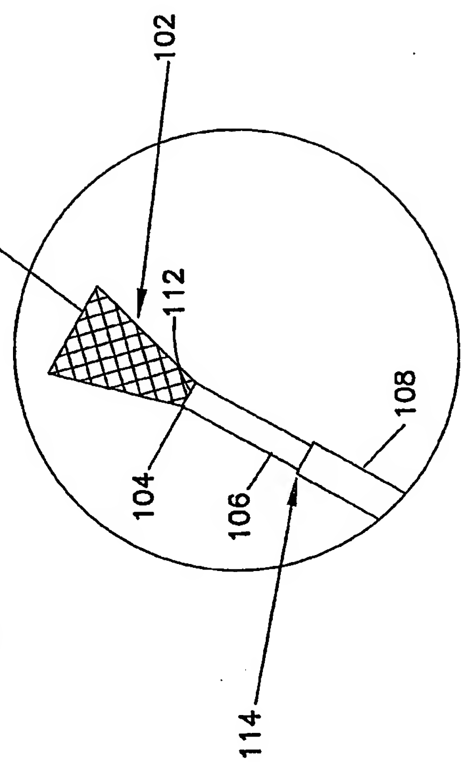
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FIG. 2

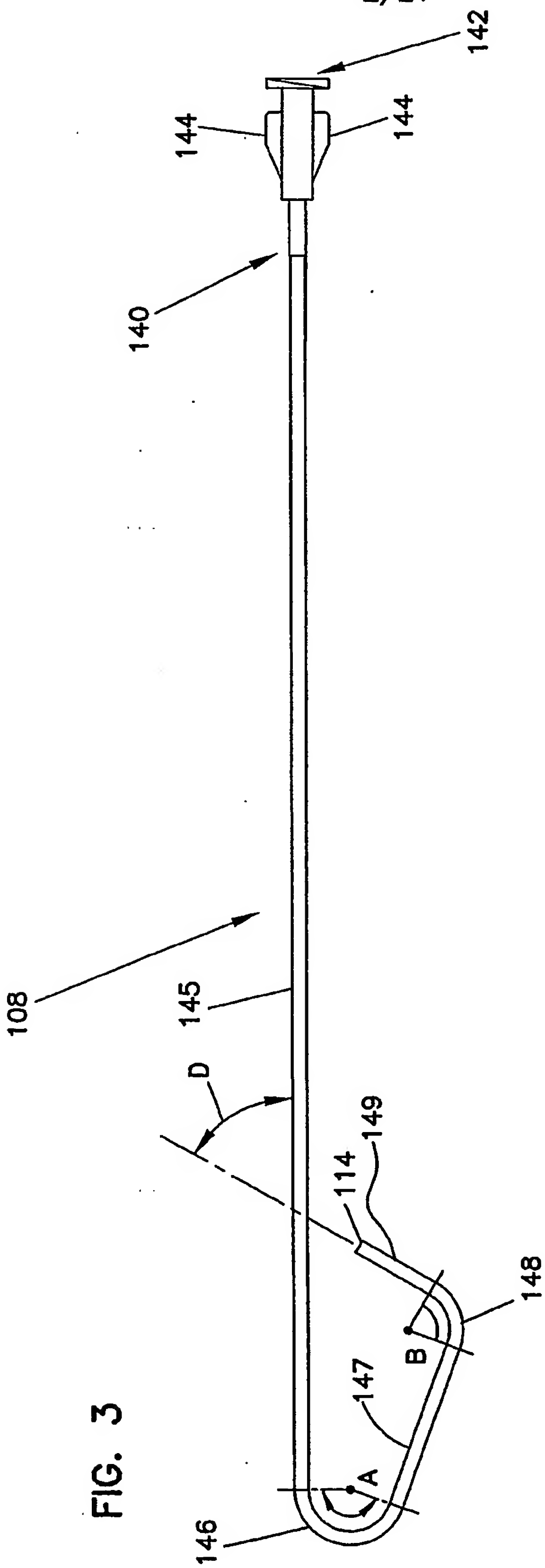
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FIG. 3

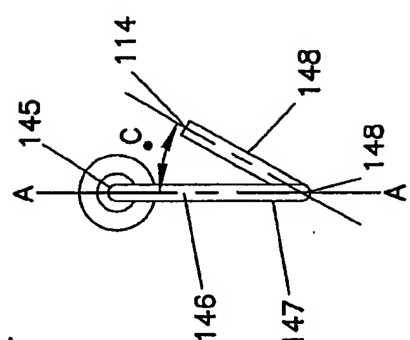
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FIG. 4

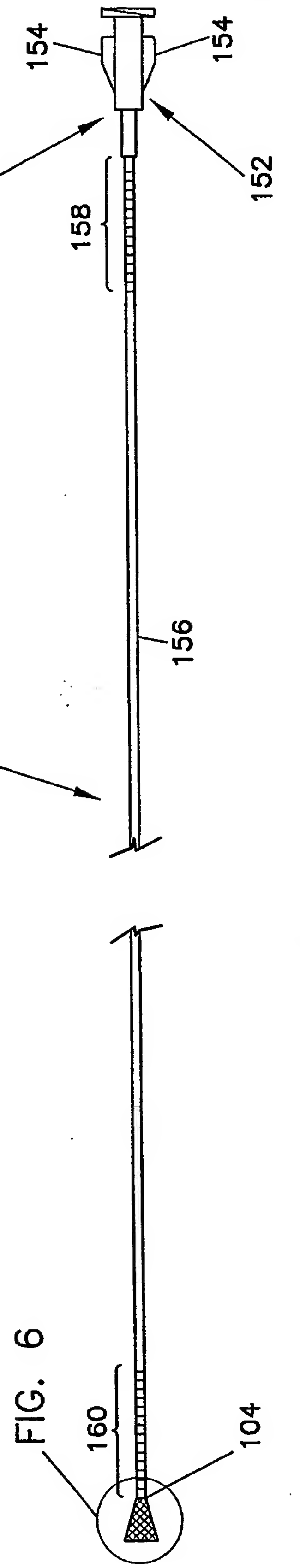


FIG. 5

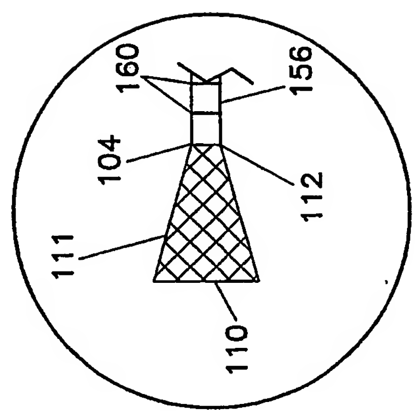
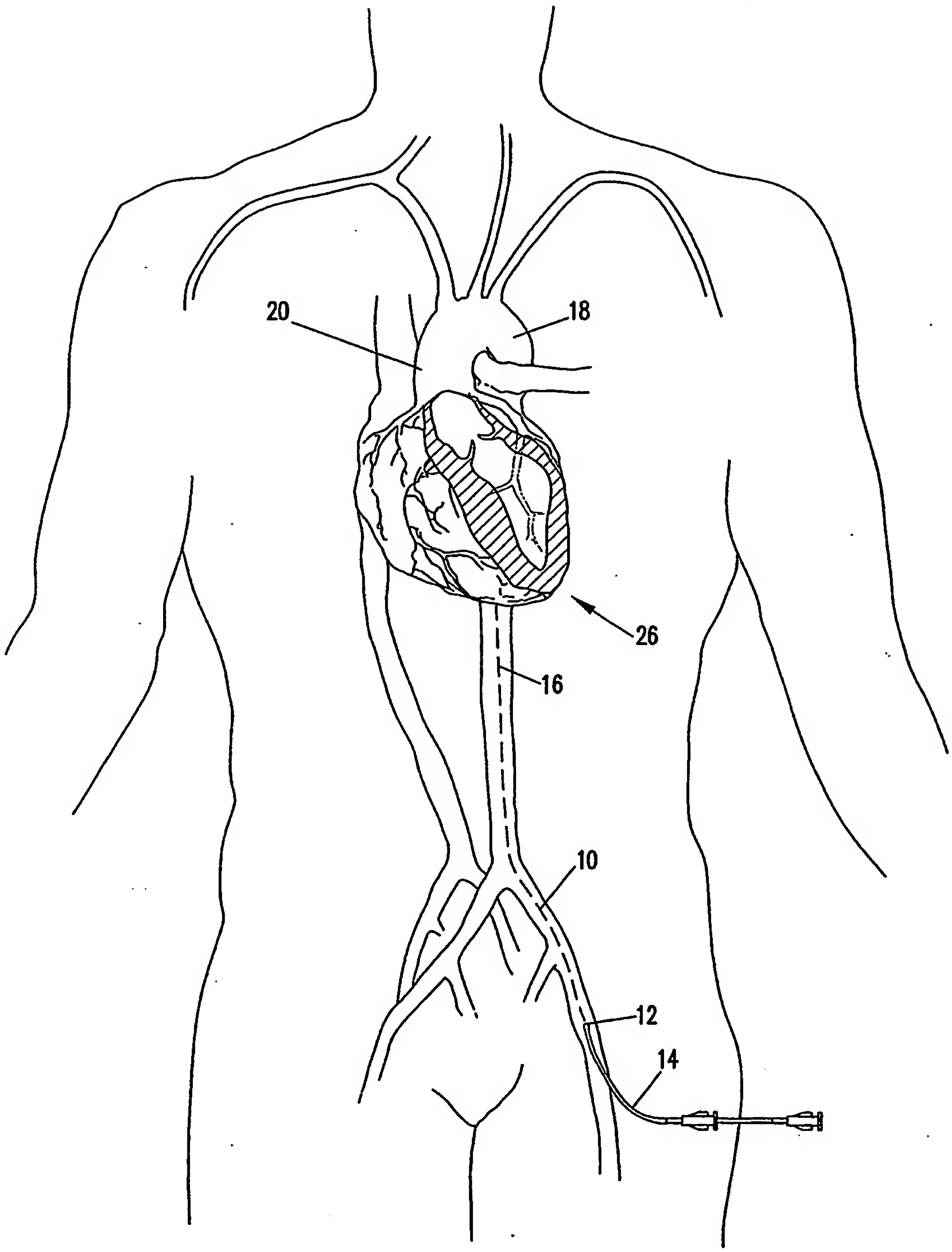


FIG. 6

FIG. 7



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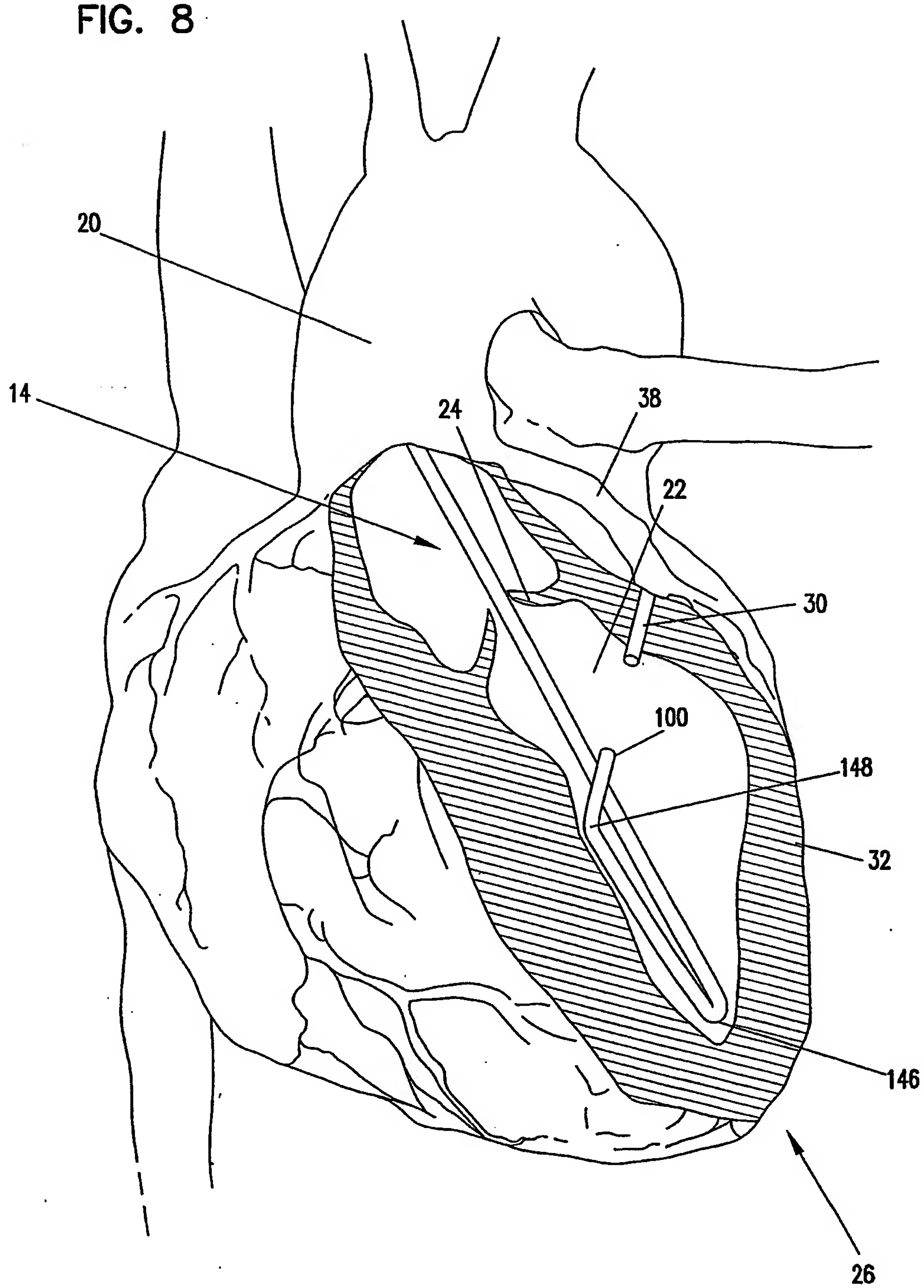

FIG. 9

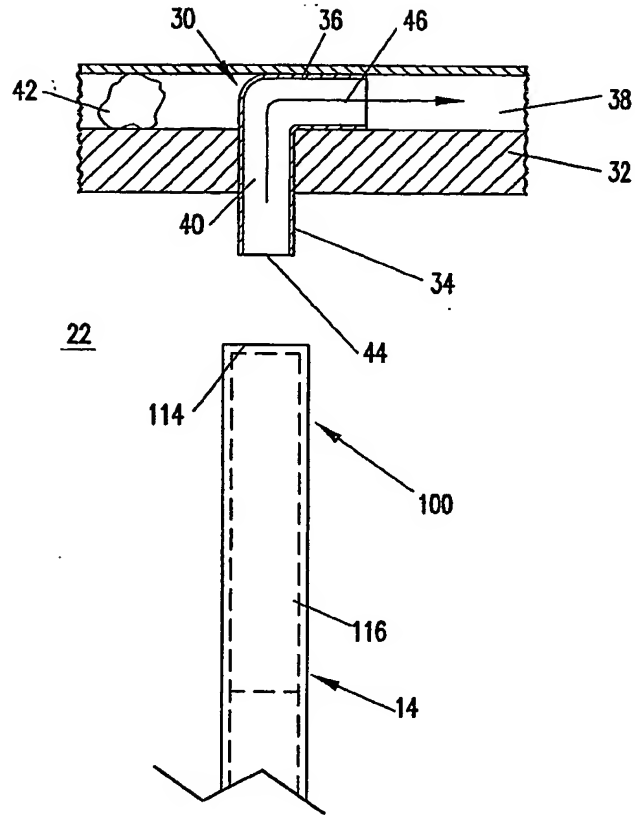
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FIG. 10

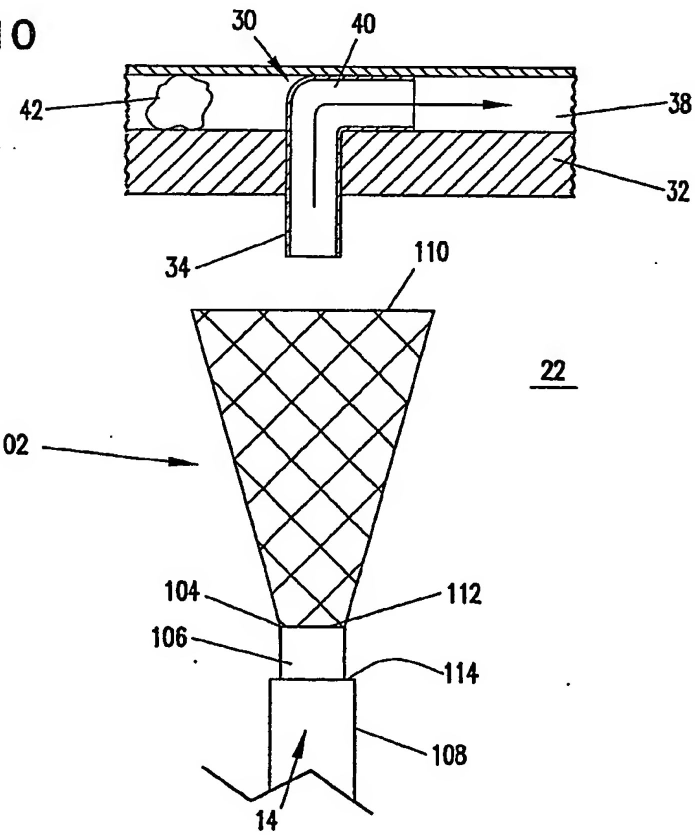
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FIG. 11

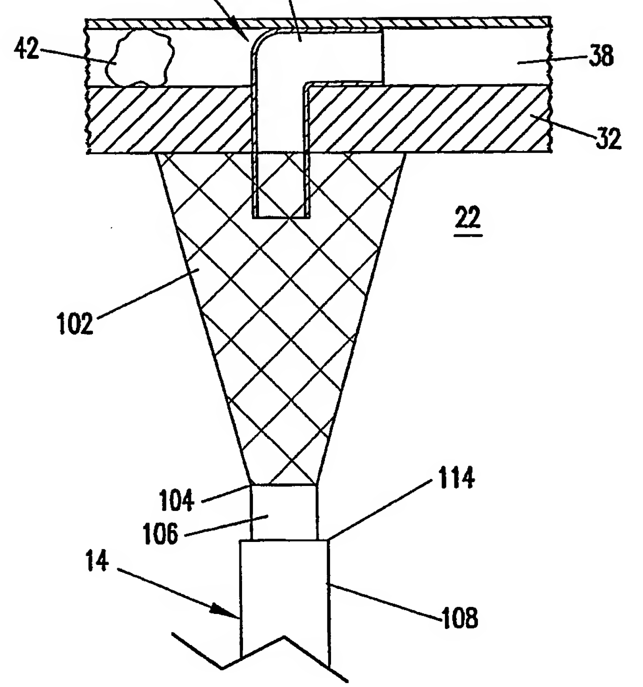
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FIG. 12

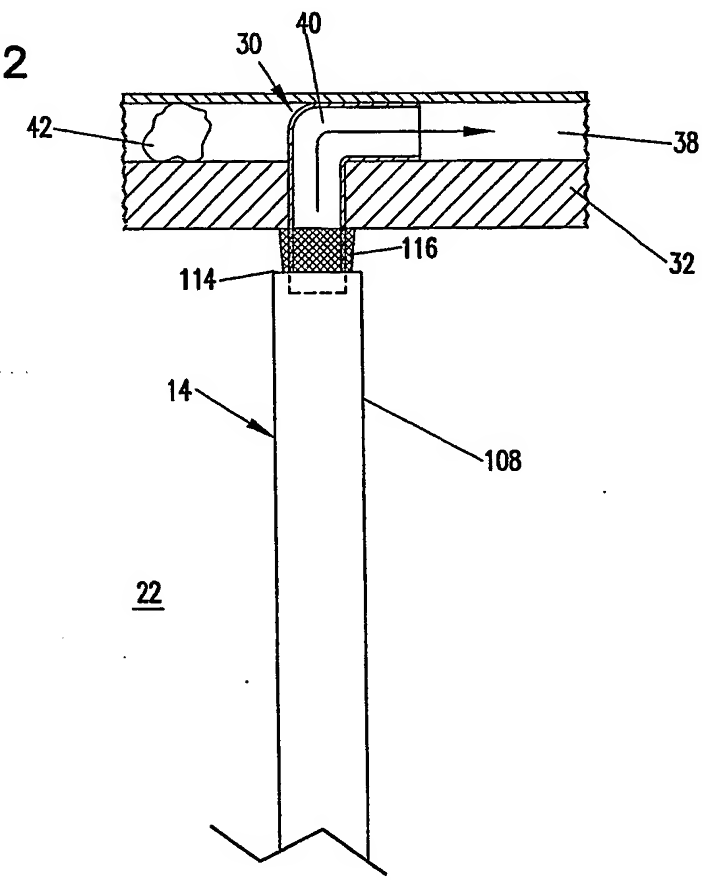
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FIG. 13

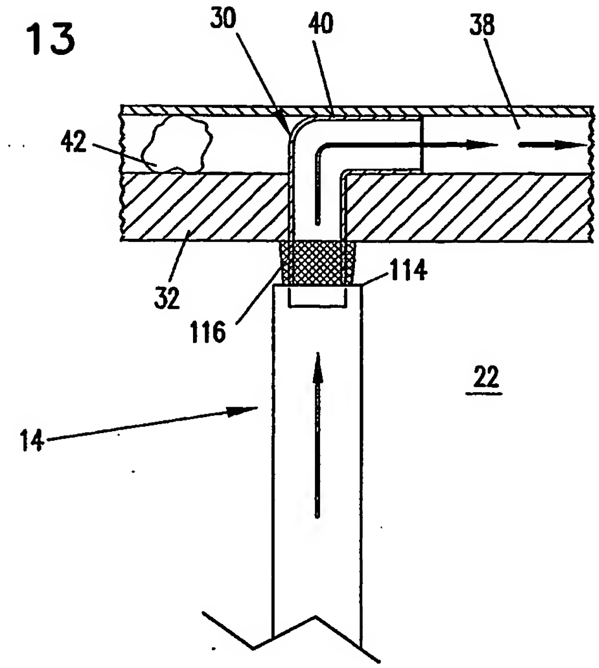


FIG. 14

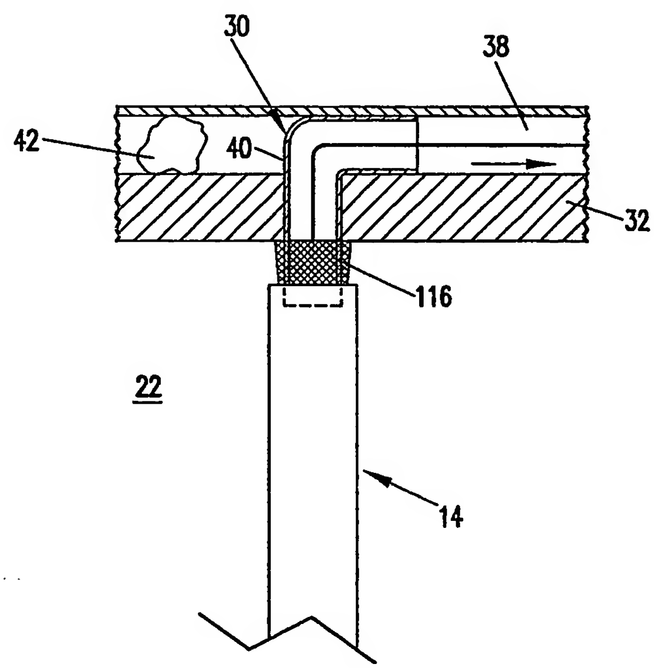


FIG. 15

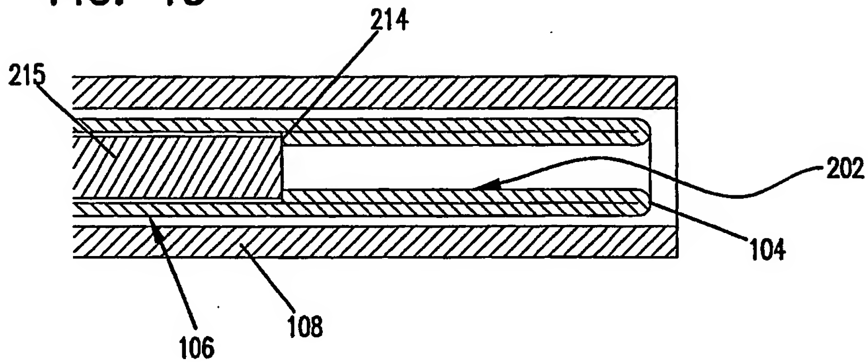


FIG. 16

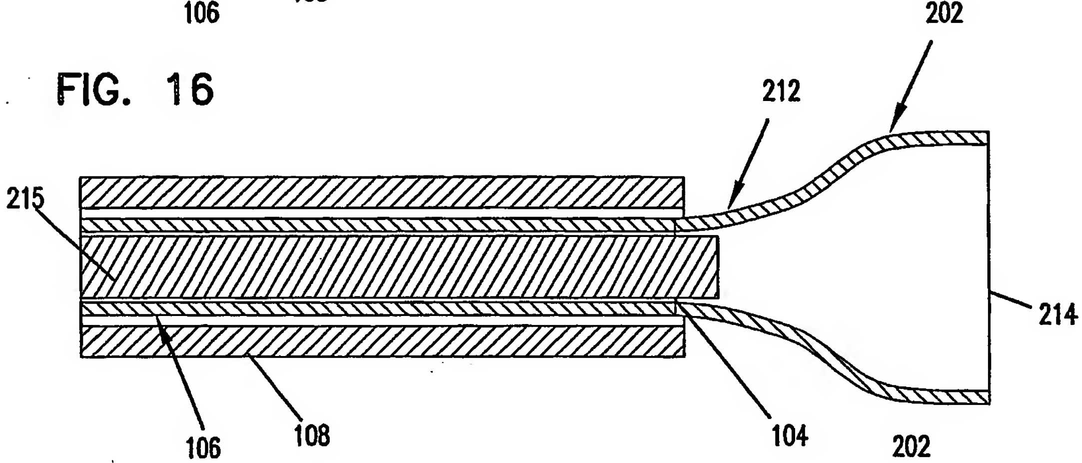


FIG. 17

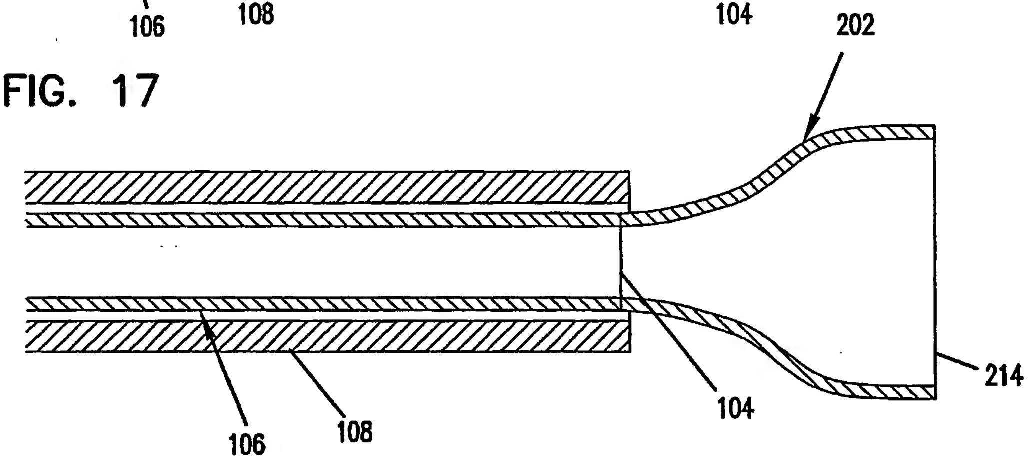
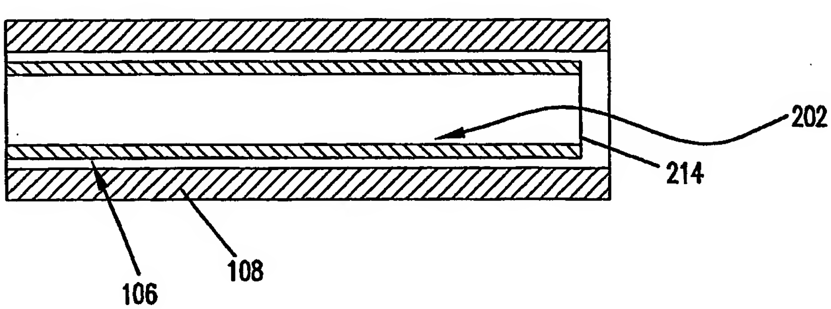


FIG. 18



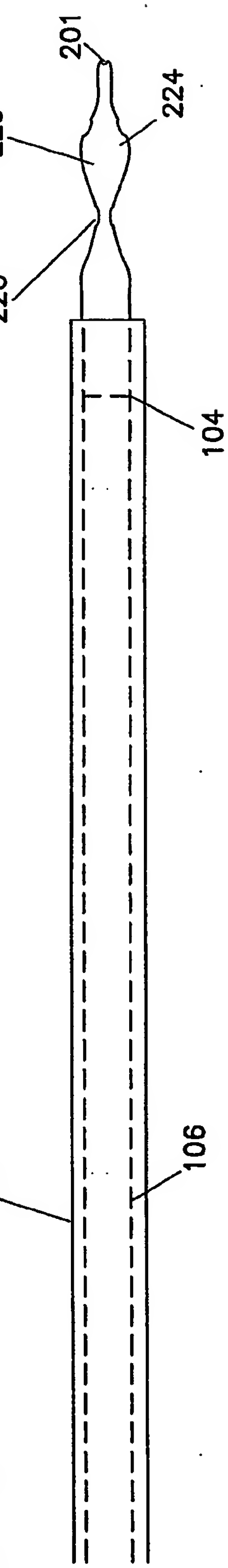


FIG. 19

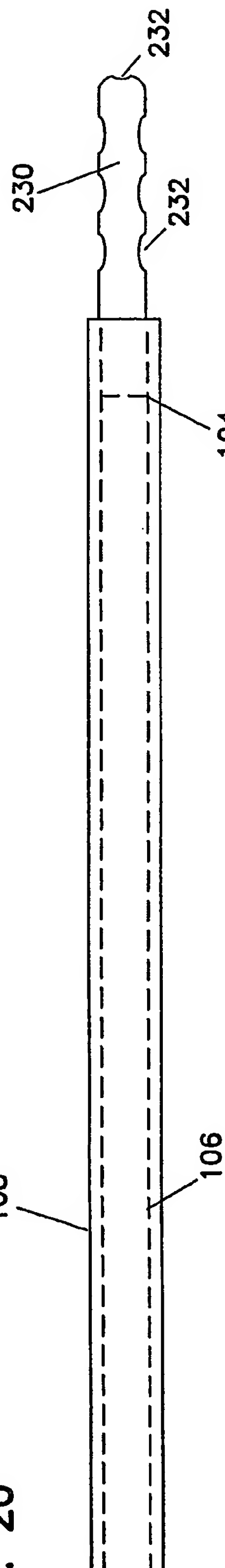


FIG. 20

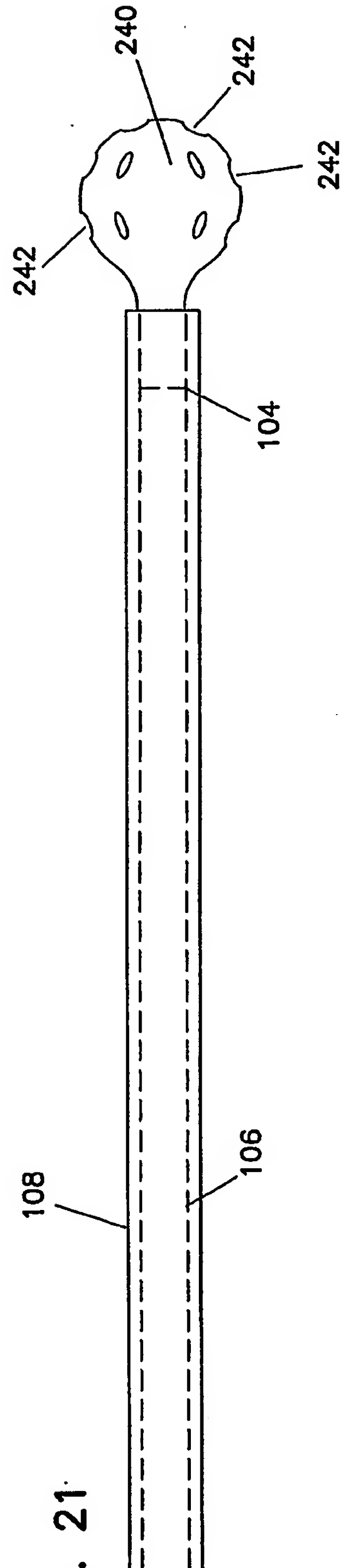


FIG. 21

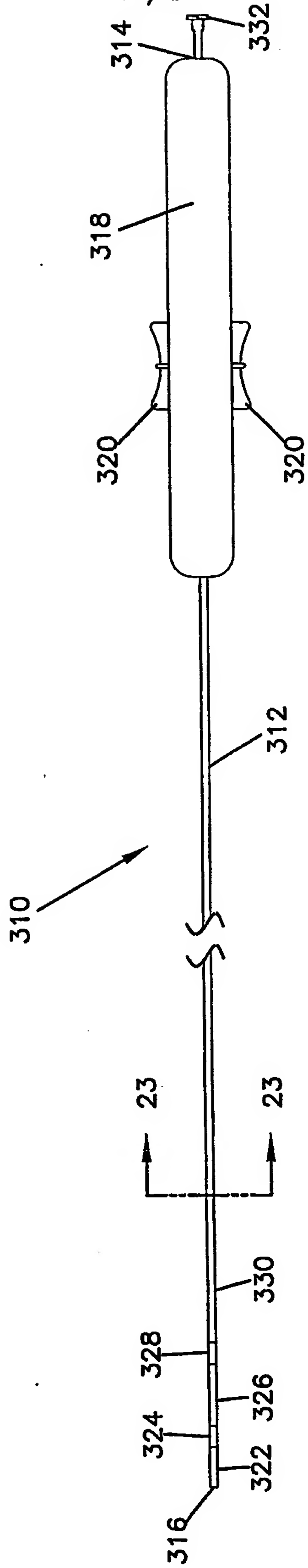


FIG. 22

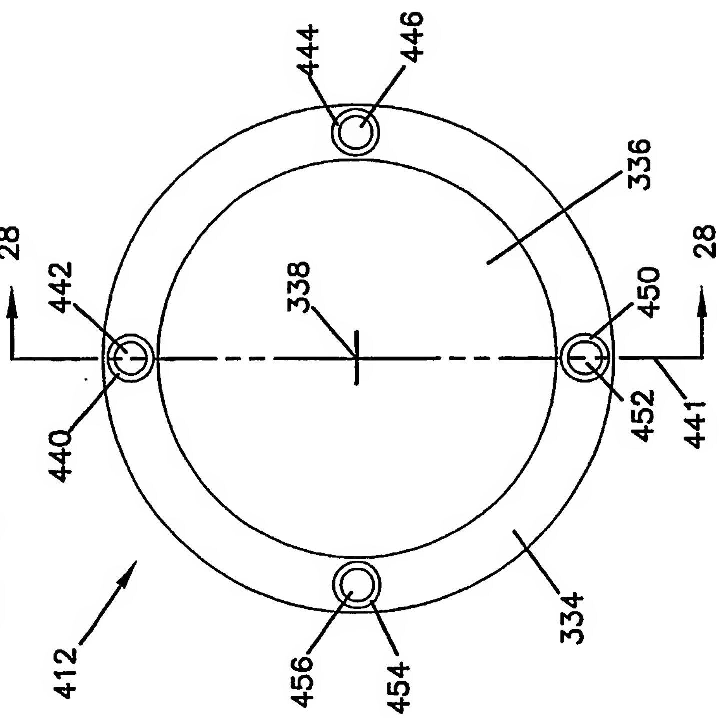

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FIG. 24

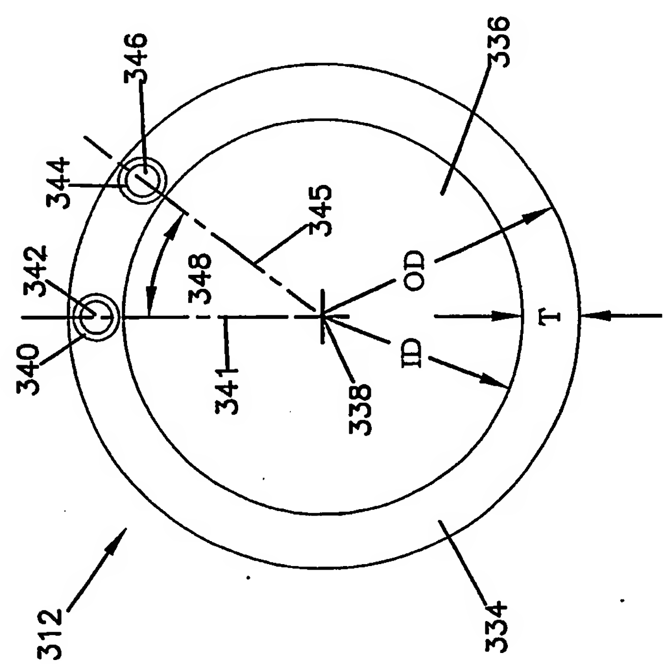
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FIG. 23

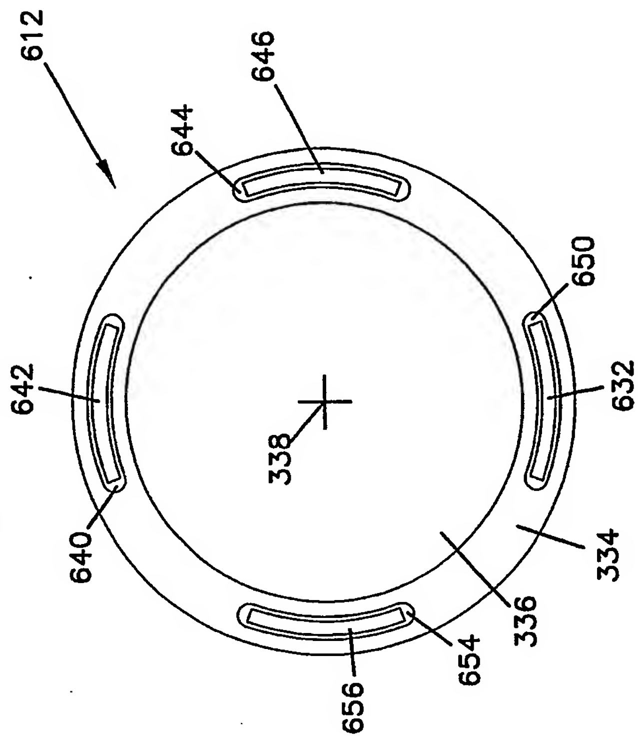
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FIG. 26

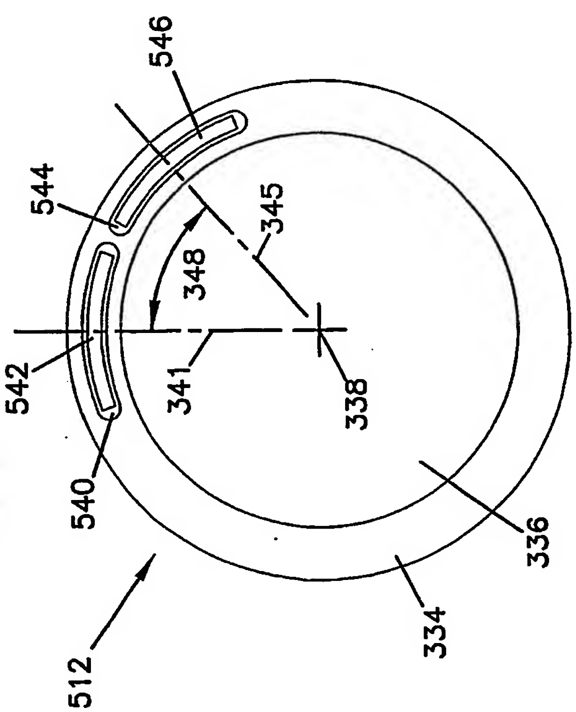
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FIG. 25

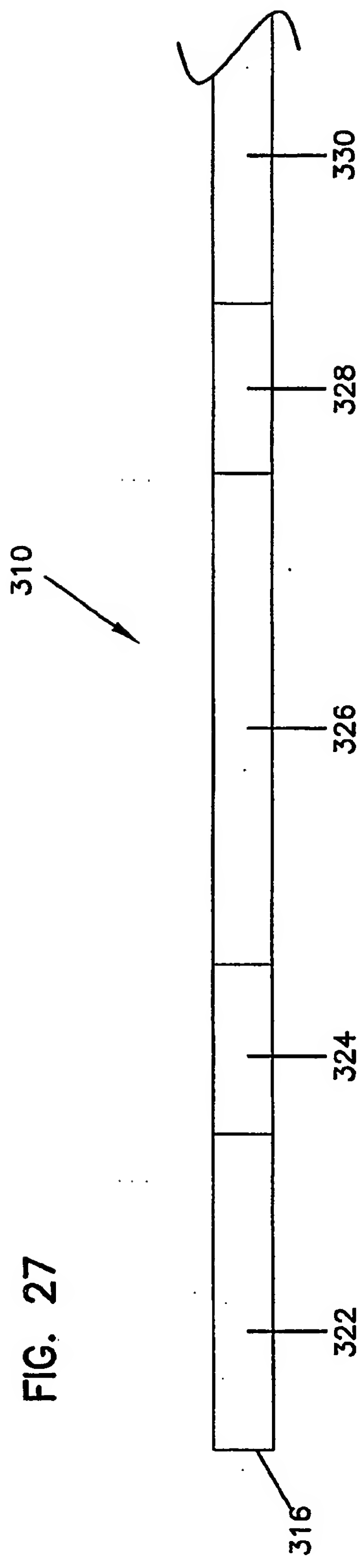
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FIG. 27

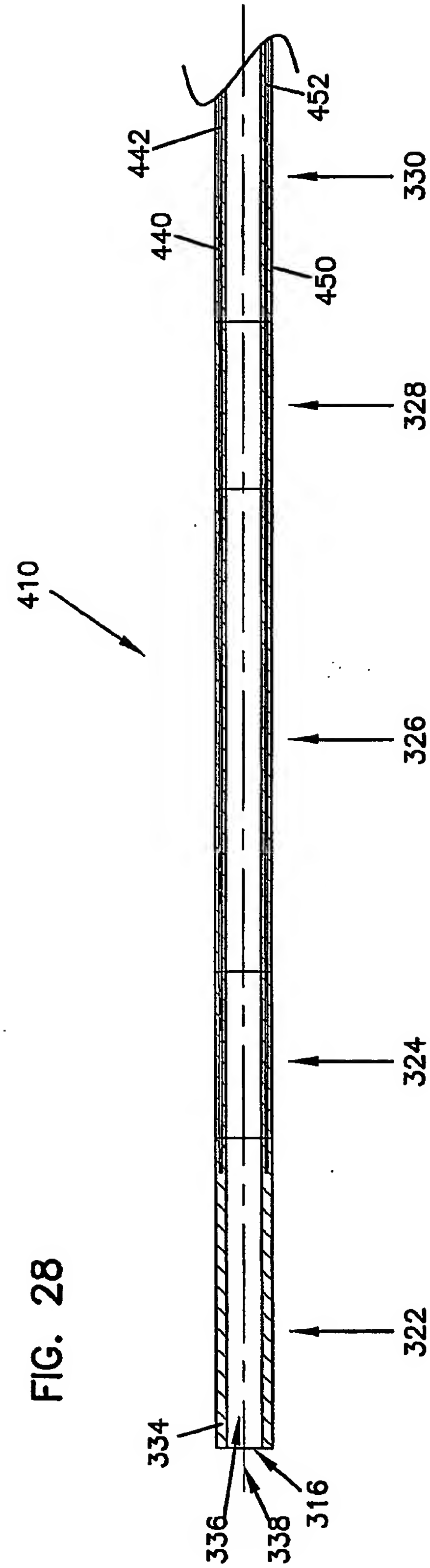
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FIG. 28

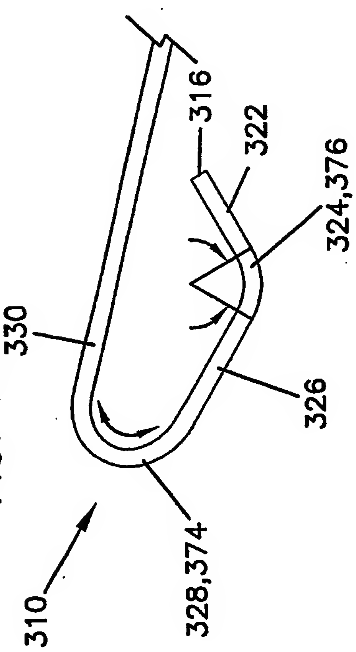


FIG. 29

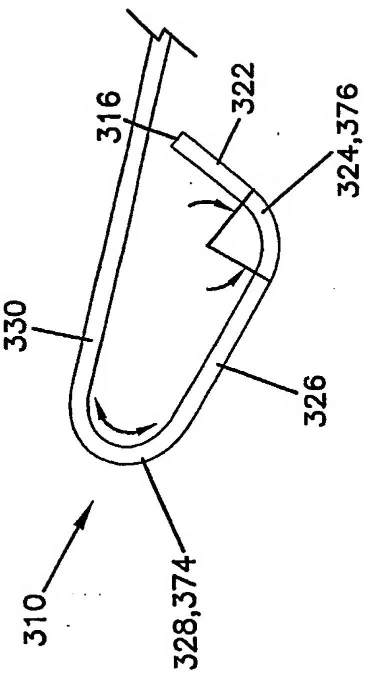


FIG. 30

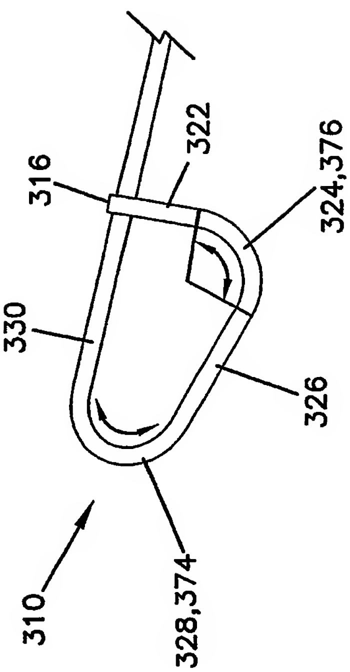


FIG. 31

FIG. 32

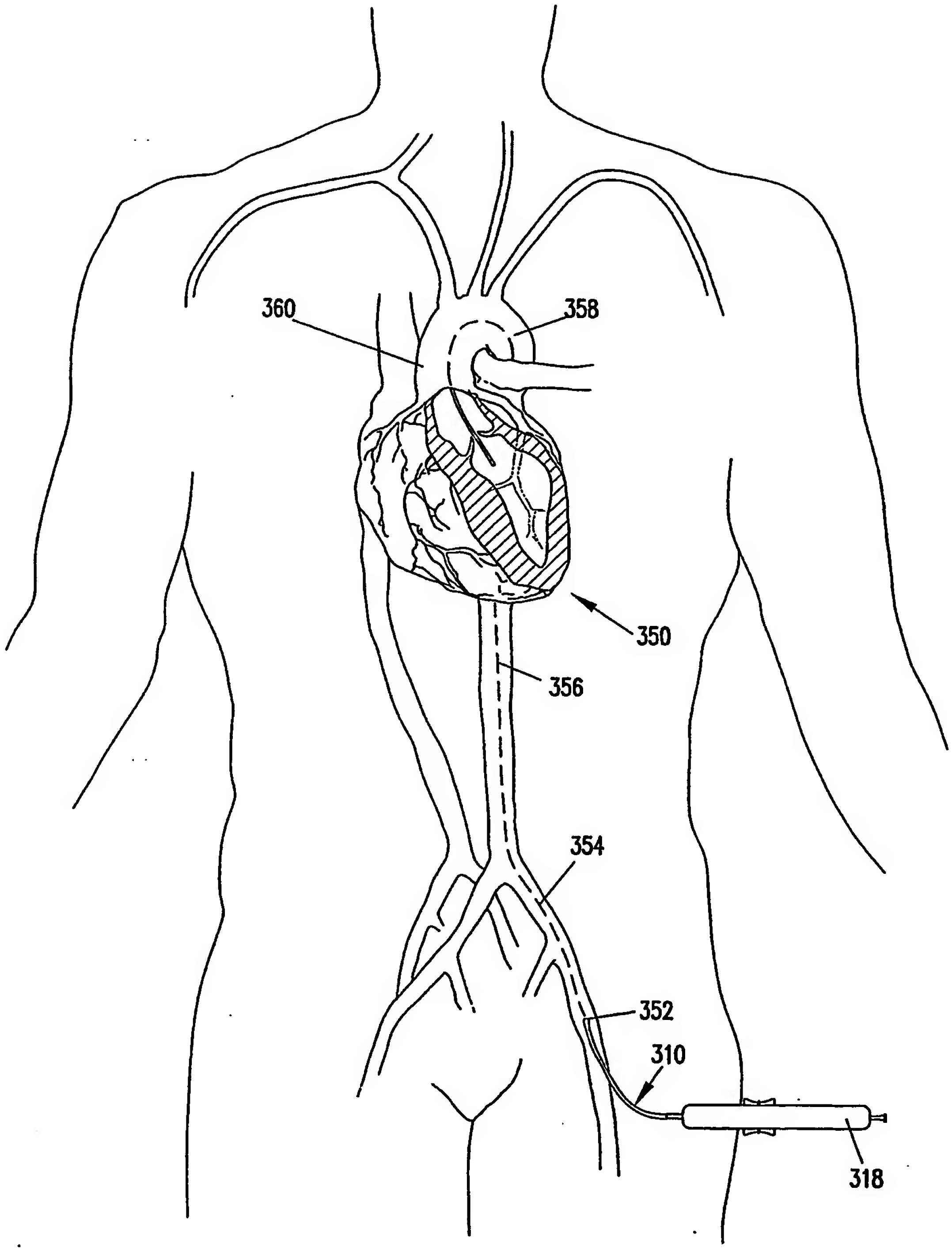
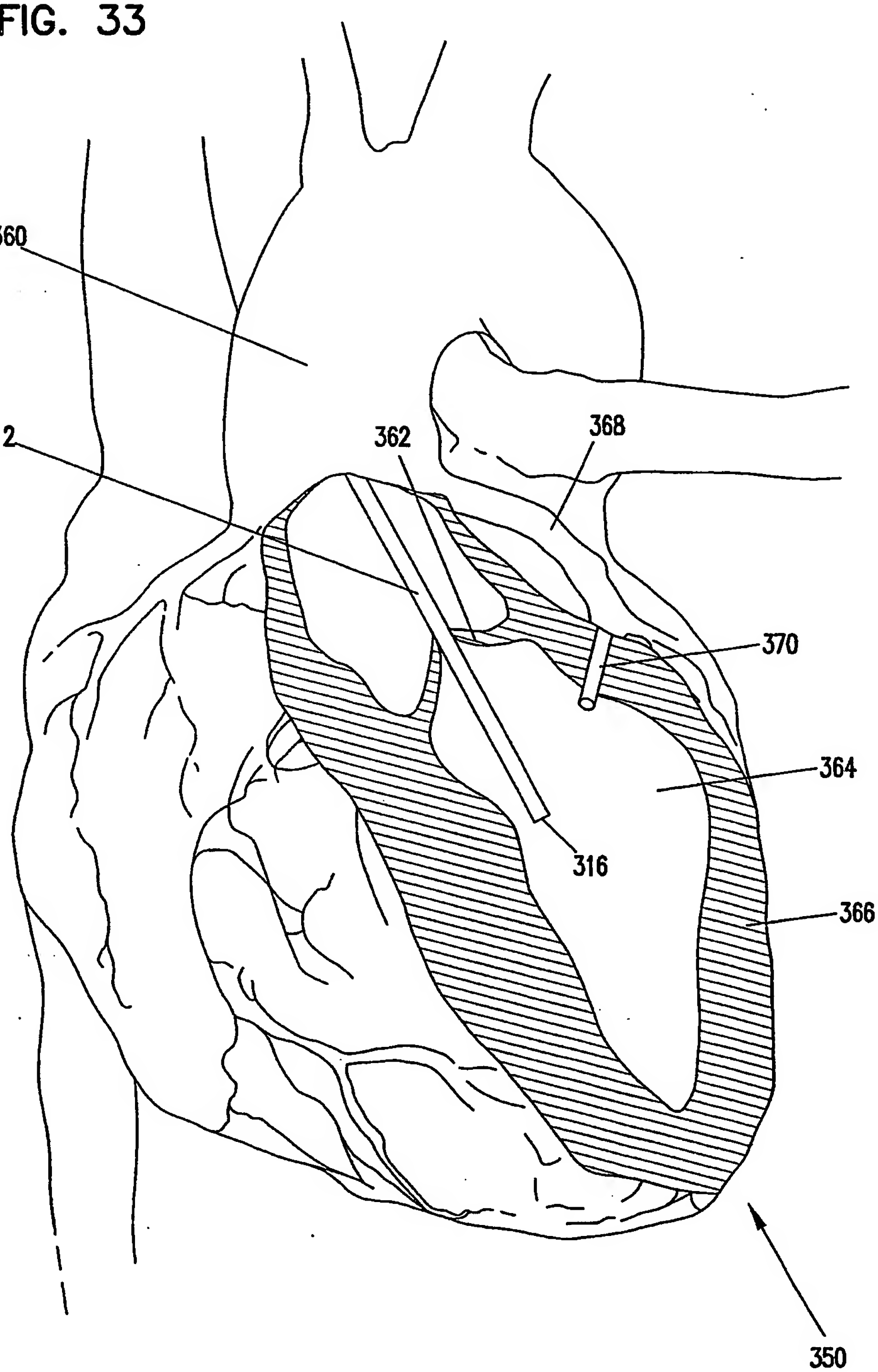
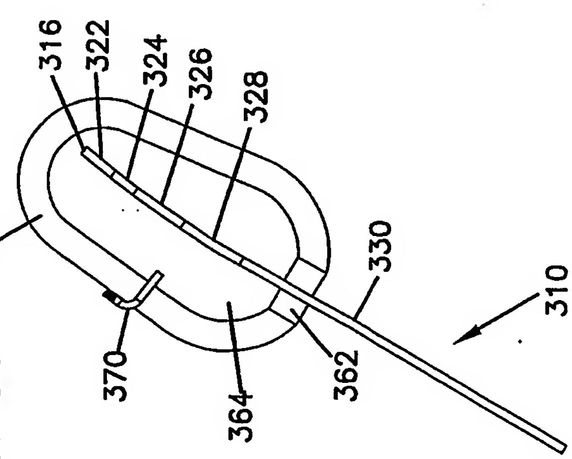


FIG. 33





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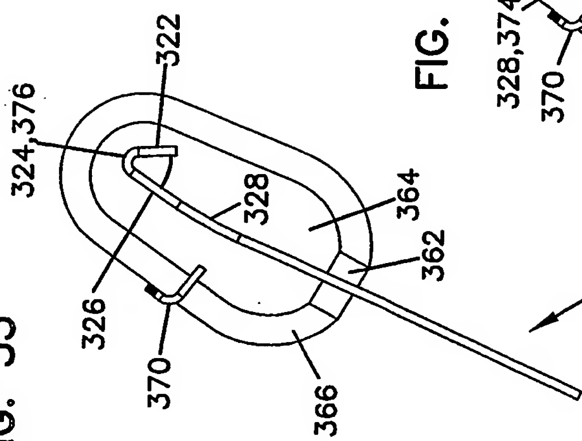

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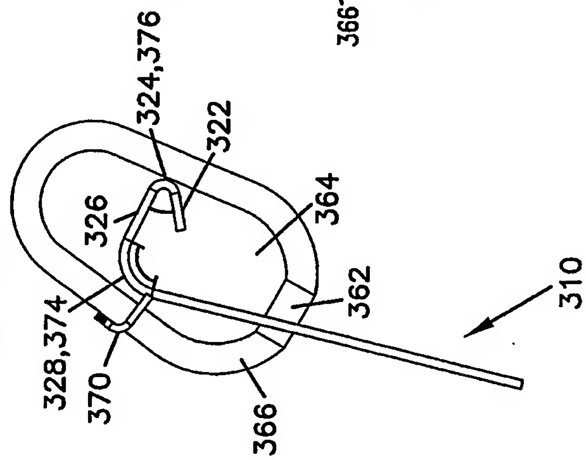

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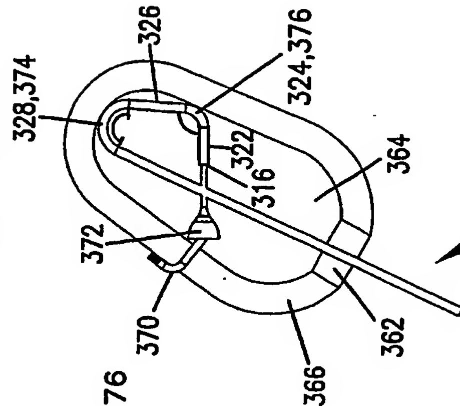

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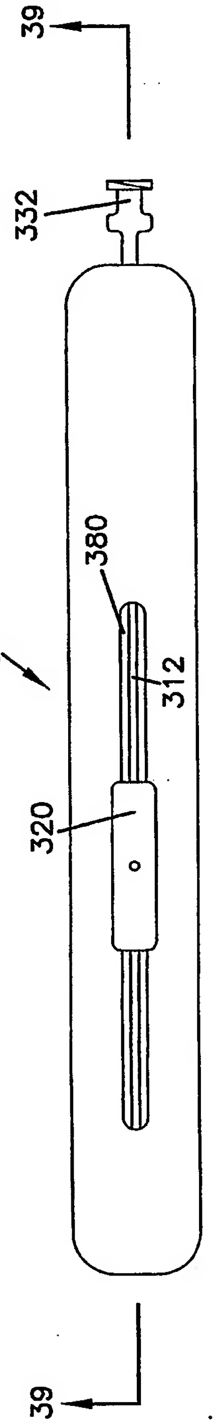
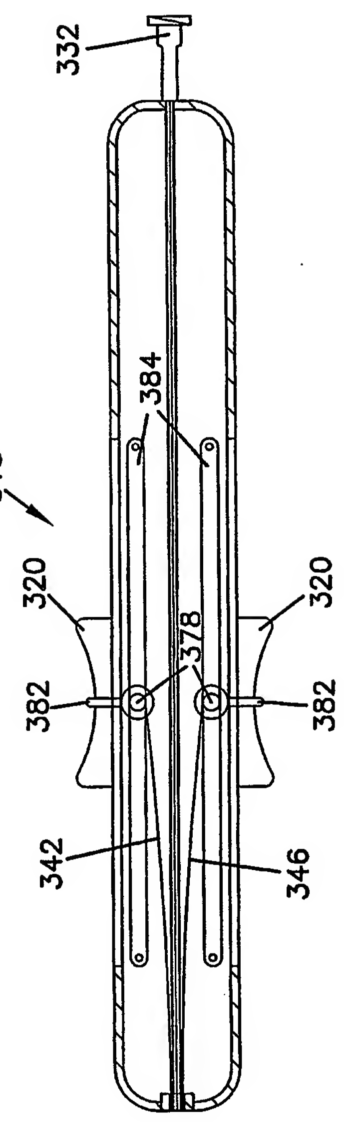


FIG. 38



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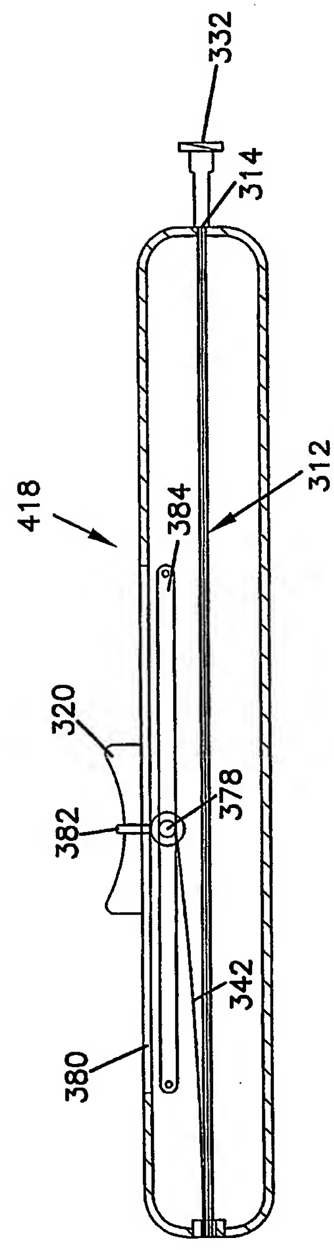

FIG. 40

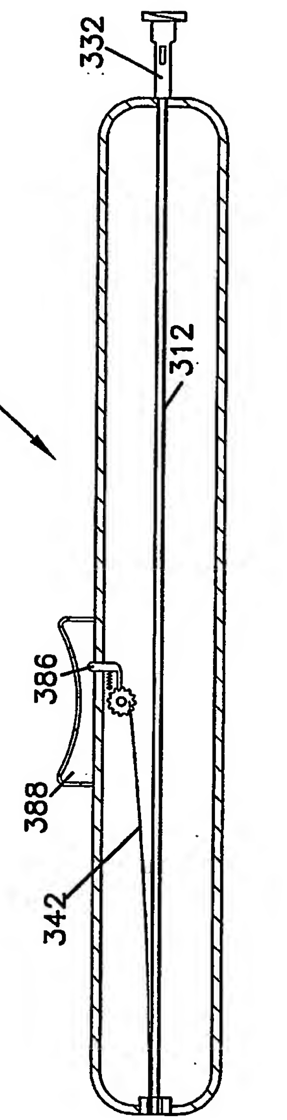

FIG. 41

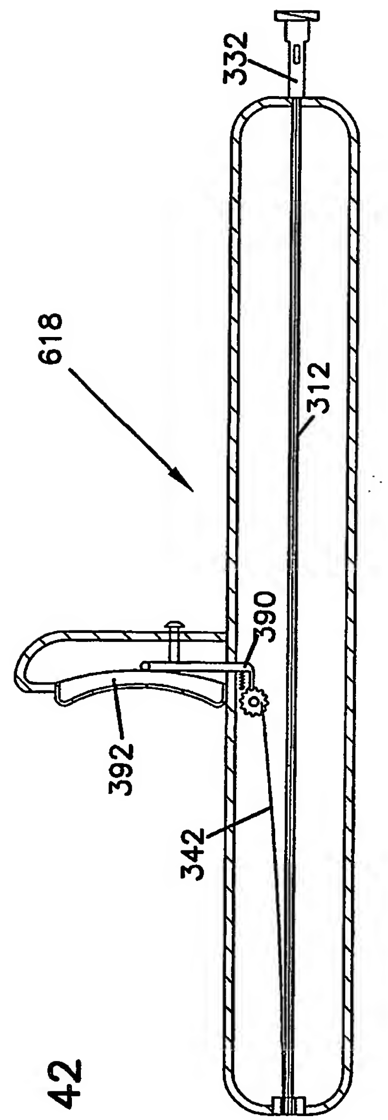

FIG. 42

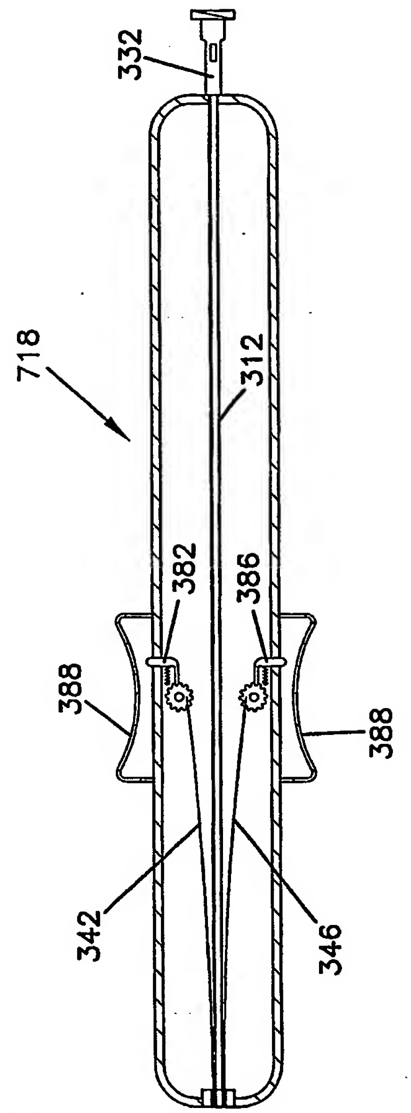
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FIG. 43

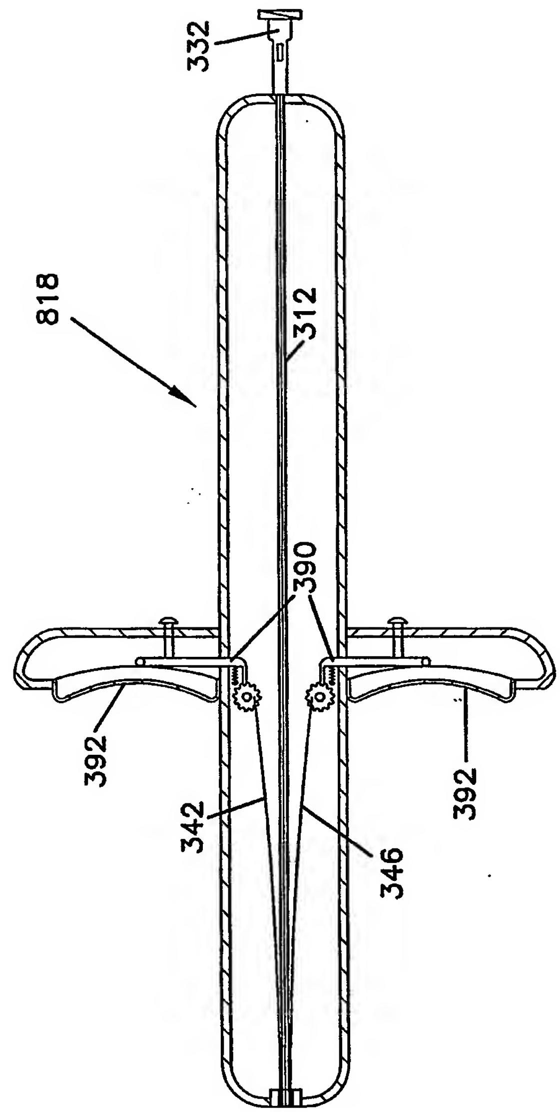
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FIG. 44

PATENT COOPERATION TREATY

PCT

DECLARATION OF NON-ESTABLISHMENT OF INTERNATIONAL SEARCH REPORT

(PCT Article 17(2)(a), Rules 13ter.1(c) and Rule 39)

Applicant's or agent's file reference 11587.34W001	IMPORTANT DECLARATION	Date of mailing (day/month/year) 19/11/2002
International application No. PCT/US 02/26226	International filing date (day/month/year) 15/08/2002	(Earliest) Priority date (day/month/year) 16/08/2001
International Patent Classification (IPC) or both national classification and IPC		A61B17/00 A61M25/00
Applicant HEARTSTENT CORPORATION		

This International Searching Authority hereby declares, according to Article 17(2)(a), that **no international search report will be established** on the international application for the reasons indicated below

1. [X] The subject matter of the international application relates to:
   - a. [ ] scientific theories.
   - b. [ ] mathematical theories
   - c. [ ] plant varieties.
   - d. [ ] animal varieties.
   - e. [ ] essentially biological processes for the production of plants and animals, other than microbiological processes and the products of such processes.
   - f. [ ] schemes, rules or methods of doing business.
   - g. [ ] schemes, rules or methods of performing purely mental acts.
   - h. [ ] schemes, rules or methods of playing games.
   - i. [X] methods for treatment of the human body by surgery or therapy.
   - j. [X] methods for treatment of the animal body by surgery or therapy.
   - k. [ ] diagnostic methods practised on the human or animal body.
   - l. [ ] mere presentations of information.
   - m. [ ] computer programs for which this International Searching Authority is not equipped to search prior art.

2. [X] The failure of the following parts of the international application to comply with prescribed requirements prevents a meaningful search from being carried out:
   [ ] the description [X] the claims [ ] the drawings

3. [ ] The failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions prevents a meaningful search from being carried out:
   - [ ] the written form has not been furnished or does not comply with the standard.
   - [ ] the computer readable form has not been furnished or does not comply with the standard.

4. Further comments: SEE FURTHER INFORMATION CONTINUED FORM PCT/ISA/203

Name and mailing address of the International Searching Authority	Authorized officer
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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 203

A meaningful search is not possible on the basis of all claims for the following reasons.

Claims 5-15,22-27,67,68 are directed to methods for treatment of the human or animal body by surgery and are therefore excluded under Rule 39.1(iv) PCT.

The present application contains 49 claims not excluded under Rule 39.1(iv). These include 9 claims presented as independent claims differing from one another by their technical content and/or in the wording used to define such technical content, and including within their scope an extremely large number of possible devices.

The large number and also the wording of the claims presently on file renders it difficult if not impossible to determine the matter for which protection is sought. As a result the present application fails to comply with the requirement, see Article 6 PCT, of clarity and conciseness, see also Rule 6.1(a) PCT, to the extent that a meaningful search is impossible. Consequently no search report can be established for the present application.

Although no formal objection concerning lack of unity has been made at this stage because of the above objection under Article 6 PCT, it would appear that several of the independent claims define inventions not linked by a single inventive concept, see Rule 13 PCT.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.